UK Data Service Study Number 855800

Identifying and mitigating the individual and dyadic impact of COVID-19 and life under physical distancing on people with dementia and carers (INCLUDE)

An additional COVID-19-specific module for the IDEAL-2 study

User guide

29/06/2022

University of Exeter Medical School, Centre for Research in Ageing and Cognitive Health (REACH)

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Funded by the Economic and Social Research Council (UK), ES/V004964/1

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Note about variables removed from the archive datasets

Due to the sensitive nature of some information and the potential for re-identification of participants, some variables were removed from the archive datasets.

These are the people with dementia variables removed from the archive dataset:

- P_Date_inc
- P_Q101_9_oth_inc

The carer variable removed from the archive dataset was C_Date_inc.

In some of the Data documents and Interview documents, for example the archived Case Report Forms (CRFs), all study variables are listed. This is for transparency and reference purposes only. The removed variables and their replacement derived variables are recorded in Data documents.

Note about archived Case Report Forms

Archived CRFs are pdf versions of the Qualtrics online surveys. They have been slightly altered for formatting reasons where Qualtrics code was used. For instance, text that participants wrote could be displayed in subsequent questions to help question administration; this code has been replaced by placeholder text. Question numbers have been replaced so that they now match the variable numbers in the datasets. Question numbering mirrors the 'Improving the experience of Dementia and Enhancing Active Life' (IDEAL) study numbering: i.e., P is used to indicate person with dementia and C is used to indicate carer. Instead of ending a question number with IDEAL timepoint, all questions end with "inc" to indicate the INCLUDE study.

The EQ-5D measure test form was removed from archived CRFs in line with the respective user agreements (see Table 1). Comments on the CRFs identify where these measures have been removed.

Table 1: Changes to measures in archived Case Report Forms and publishers' details

Title of Measure	Publishers' Details
EQ-5D	EQ-5D™ is a trademark of the EuroQol Group. Without the prior written consent of the EuroQol Group Executive Office, it is not permitted to i.e., use, reproduce, alter, amend, convert, translate, publish or make available in whatever way (digital, hard-copy etc.) the EQ-5D and related proprietary materials. All copyrights in the EQ-5D, its (digital) representations, and its translations exclusively vest in the EuroQol Group Foundation.

Document History

Version Number	Effective Date	Authorship	Summary of changes
1	29/06/2022	Madhumathi Ravi	New document.

1. Summary of documentation in the archive

The documentation in UK Data Service study number (SN) 855800 has been organised as follows:

User guide

- Overview of documentation in the archive.
- Study design and implementation.
- Data collection and data processing.
- Advice on dataset use and how to cite the data.
- Acknowledgements and study publications.

Data documents

- List of variables ordered into categories (best place to start for analysing data).
- Measures ordered into categories and their citations.
- Data dictionaries of variables in the order they appear in the datasets.

Interview documents

- Case Report Forms (CRFs) mapped to dataset variables.
- Study consent forms.
- Interview schedules.

Supporting documents

- Study protocol.
- Invitation letters.
- Participant information sheets.
- Consent forms.
- Demonstration of capacity checklist.
- Adverse event reporting form.

2. Introduction to INCLUDE, a COVID-19 arm of the IDEAL programme

INCLUDE is a mixed-methods cross-sectional observational study embedded in, and forming a discrete component of, the ongoing longitudinal research with the 'Improving the experience of Dementia and Enhancing Active Life' (IDEAL) cohort. The IDEAL programme is a 10-year programme incorporating a longitudinal cohort study of people with dementia and primary carers (carers) across Great Britain.

INCLUDE added a COVID-19-specific data-collection module to the nationwide IDEAL-2 study. INCLUDE was funded by the Economic and Social Research Council (ESRC) through Grant ES/V004964/1 under the UK Research and Innovation (UKRI) open call for research and innovation ideas to address COVID-19.

INCLUDE aimed to identify the impact of COVID-19 and resulting physical distancing measures on people with dementia and their carers. Linking COVID responses to pre-COVID data is possible using IDEAL Timepoints 1-3 (T1-T3) data. INCLUDE participants were people with dementia and carers that took part in IDEAL and IDEAL-2; at the time of archiving the INCLUDE datasets IDEAL data are currently available (https://reshare.ukdataservice.ac.uk/854293/) but not IDEAL-2 data.

The primary aim of INCLUDE was to understand the impact of COVID-19 and concomitant physical restrictions on IDEAL participants. Assessments were conducted remotely due to COVID-19 restrictions. Variables comprised mostly individual items from measures that were included in IDEAL and/or IDEAL-2: this was to reduce the added burden on participants anticipated as a result of using remote assessment, which, up until INCLUDE, had not been employed by IDEAL to assess participants. In INCLUDE, cognition was assessed using a different measure to that used in IDEAL due to remote administration: the five-minute Montreal Cognitive Assessment (MoCA) [1], specifically designed to be administered remotely, was used in place of the Mini-Mental State Examination (MMSE). Scores on the 5-minute MoCA can be converted into an estimated MMSE score [2].

The study also included some bespoke COVID-19-related items; these were taken or adapted from questions used in the English Longitudinal Study of Ageing COVID study (https://doi.org/10.5255/UKDA-SN-8688-3) or were created by the INCLUDE research study team. The purpose of including English Longitudinal Study of Ageing items was to allow for cross-study comparison.

INCLUDE participants comprised 172 people with dementia and 288 carers living in England and Wales. Separate interviews were conducted for people with dementia and carers. Interviews with people with dementia were carried out over the telephone or via videoconference. All responses were recorded by researchers using an online survey designed in Qualtrics. Carers were either interviewed in a similar way or self-completed an online form in their own time. Data were stored in Qualtrics.

The study was co-ordinated at the University of Exeter Medical School Centre for Research in Ageing and Cognitive Health (REACH). Professor Linda Clare is the Chief Investigator of INCLUDE and the IDEAL programme. Full acknowledgements are listed in Section 7. Acknowledgements.

3. INCLUDE study design

3.1 Overview

INCLUDE was a mixed-methods cross-sectional observational study embedded in, and forming a discrete component of, the ongoing longitudinal research with the national IDEAL cohort. Participants completed questionnaires and responded to open-ended questions in a structured interview. A small sub-set completed a semi-structured interview. All interviews were conducted remotely.

INCLUDE was a cross-sectional study that took place between Timepoint 4 (T4) and Timepoint 6 (T6) of IDEAL-2 data collection. Due to the start of the COVID-19 pandemic, T4 data collection was not fully completed and Timepoint 5 (T5) data collection, which had just started, had to be discontinued. Assessments for INCLUDE took place between September 21st, 2020, and April 30th, 2021.

The interviews for both people with dementia and carers were designed to be completed in one visit lasting approximately one hour. Most participants completed the interview in a single visit, but some took more than one visit.

All participants who took part during IDEAL T3 or who had taken part in IDEAL-2 T4 and/or T5 were contacted. In total, 624 eligible people with dementia and 584 eligible carers were identified. Of these, 109 people with dementia and 88 carers could not be contacted. Of the remaining 515 people with dementia and 496 carers, 343 people with dementia and 208 carers did not participate; Table 2 outlines the reasons for not taking part. The number of people who took part in INCLUDE was 173 people with dementia and 288 carers. One person was subsequently removed from the people with dementia dataset due to a change in diagnosis; this person did not have a carer involved in the study. The final number of participants with dementia was therefore 172.

Table 2: Reasons given by people with dementia and/or carers for not taking part

Reason for not taking part	People with dementia	Carers
Death of the participant	64	6
Death of the care recipient (where the carer was participating but not the person with dementia)	-	72
Too impaired	106	-
Unwell	9	10
Declined remote assessment	45	8
Moved into care	51	-
Lacked capacity to give consent	10	-
Declined to take part without giving a reason	58	104
Agreed to self-complete but did not	-	8

Interviews comprised questions about demographic details, single items taken from existing standardised measures and ratings, and new measures developed for the study. A comprehensive list of measures and citations are found in the Data documents.

3.2 Timetable

INCLUDE interviews took place between September 21st 2020 and April 30th 2021. There were significant changes to COVID-19 restrictions during this time and in some cases, these varied regionally or locally; two variables are included in the datasets that record the current level of restrictions that were in place for each participant at the time of the interview. As a general guide these are recorded as:

England

1 England Localised restrictions: 2nd June – 4th November 2020

2 England National Lockdown 2: 5th November – 2nd December 2020

3 England Localised restrictions: 3rd December 2020 – 4th January 2021

4 England National Lockdown 3: 5th January – 7th March 2021

5 England Covid Spring response 2021 (gradual easing of restrictions): 8th March – April 30th 2021

Wales

6 Wales local restrictions: 2nd June – 22nd October 2020

7 Wales "firebreak" lockdown (Lockdown 2): 23rd October – 9th November 2020

8 Wales local restrictions: 10th November – 15th December 2020

9 Wales National Lockdown 3: 16th December 2020 – 14th March 2021

10 Covid Spring response 2021 (gradual easing of restrictions): 15th March – April 30th 2021

3.3 Sample design

There were no specific inclusion criteria as all participants were already taking part in the IDEAL programme. No new participants were recruited into the study, other than new carers who replaced the original carer that had taken part at earlier timepoints of IDEAL. People with dementia could take part if there was no carer taking part, and carers could take part if the person with dementia was no longer willing or no longer able to take part. The only exclusion criterion was a lack of capacity to give informed consent on the part of the person with dementia. People with dementia residing in care homes could not be contacted to take part so only community dwelling people with dementia took part in INCLUDE.

Table 3 outlines the number of people with dementia and carers who took part for different sub-groups based on diagnosis, age, sex, living situation, and relationship with the carer.

Table 3: INCLUDE sample characteristics for people with dementia and carers

	People with dementia dataset	Carer dataset
Dementia sub-type	n	n
Alzheimer's disease (AD)	77	139
Vascular dementia	18	27
Mixed AD and vascular dementia	26	47
Frontotemporal dementia	23	33
Dementia with Lewy bodies	8	12
Parkinson's disease dementia	14	21
Other	6	9
Age distribution	n	n
< 65	29	75
65 – 69	25	55
70 – 74	30	62
75 – 79	32	37
80+	56	59
Sex	n	n
Women	71	195
Men	101	93
Living situation	n	n
Living with others	135	-
Living alone	37	-
Relationship with primary carer	n	n
Spouse/partner	108	236
Other family/Friend	18	52
No carer in study	46	-
Person with dementia no longer in study	-	162

3.4 Patient and Public Involvement (PPI)

PPI was led by Innovations in Dementia with support from Alzheimer's Society and conducted in line with INVOLVE guidance. The ALWAYs ('Action on Living Well: Asking You') group was set up to provide PPI input to the IDEAL programme. ALWAYs is an involvement group of people with dementia and carers. The ALWAYs group was formed in 2014 at the start of the IDEAL programme and members have advised on different aspects of the programme, based on personal experiences, skills, and expertise.

The ALWAYs group was consulted from the beginning of the study, particularly concerning the content of the INCLUDE interviews.

The involvement of people with dementia and carers ensured that the study processes, materials, and emerging outcomes were clear and relevant. The ALWAYs group has brought enormous benefits and made

a very significant contribution to the development, implementation, analysis, interpretation, and dissemination of the IDEAL programme. This is also the case for INCLUDE.

3.5 Recruitment process

All people with dementia who were approached to take part in INCLUDE had previously taken part in the IDEAL cohort. There were a few carers that were new to the study, but most carers had taken part previously in IDEAL. The IDEAL cohort comprised people who had taken part in IDEAL and an enrichment cohort of participants that were newly recruited into IDEAL-2 at T4. The enrichment cohort was designed to increase the numbers of people with rarer types of dementia and other characteristics that were underrepresented in the original IDEAL cohort. The enrichment cohort comprised people with any dementia under the age of 65, people with any dementia over the age of 90, and people with frontotemporal dementia, Parkinson's disease dementia, or dementia with Lewy bodies.

As the COVID-19 lockdown interrupted IDEAL-2 T4 and T5, both timepoints were halted in March 2020. At T3, the number of participants in IDEAL was 851 people with dementia and 759 carers. At T4, the number of participants returning to IDEAL was 253 people with dementia and 243 carers, and the number of people newly recruited into the enrichment cohort was 204 people with dementia and 173 carers. All participants who took part at T3 and/or T4, and the few who had started T5 at the time of the first COVID-19 lockdown, were approached to take part in INCLUDE. The 29 NHS sites that undertook recruitment and assessments for IDEAL-2 updated the records of participants to ensure that any that had died or otherwise withdrawn were not contacted. In total, 624 eligible people with dementia and 584 eligible carers were identified. Ethical approval was obtained from Wales Research Ethics Committee 5 as an amendment to IDEAL-2 for England and Wales (18/WS/0111 AM12). As ethical approval is separate in Scotland and there were only small numbers of people residing in Scotland still in the cohort, only participants who resided in England and Wales were approached to take part in INCLUDE.

As face-to-face interviews were no longer permitted due to COVID-19 restrictions, three researchers were appointed at the University of Exeter to take consent and conduct the structured interviews for INCLUDE. Potential participants were primarily contacted by telephone to see if they were interested in taking part in INCLUDE. If there was no answer after three attempts an invitation letter and reply slip was sent to the last known address. Participants that expressed an interest were provided with the participant information sheet. If people with dementia were still happy to take part after having read the information sheet, their preferred interview method (telephone or video call) was established, and a date and time for the interview was agreed. Consent was taken at the start of the interview, and the structured interview followed; both were audio recorded. The consent process was the same for carers. However, an audio-recording of the semi-structured interview was not obtained for those carers who opted to self-complete their questionnaire online.

4. Data collection

4.1 Overview

Researchers undertook study-specific training before any data was collected and were subsequently independently assessed to ensure consistency of assessments. Completion of training was recorded, and details stored in a training booklet. Researchers completed courses in Information Governance, Information Security for Researchers, Research Integrity, Informed Consent Fundamentals, and Good Clinical Practice (GCP), and copies of their completion certificates for these courses were stored in the Study Master File. Bespoke training on assessing capacity to consent was also provided.

4.2 GCP, Data Protection Act, and Mental Capacity Act

Some principles of GCP, data protection, and mental capacity were disseminated during researcher training. These are listed below to give some context about how these important legislative issues were addressed during researcher training.

Good Clinical Practice – some principles:

- Each individual involved in conducting a Study should be qualified by education, training, and experience to perform his or her respective tasks(s).
- The rights, safety, and well-being of the Study participants shall prevail over the interests of science and society.
- The necessary procedures to secure the quality of every aspect of the Study shall be complied with.
- Research studies shall be conducted in accordance with the principles of the Declaration of Helsinki – which states that respect for the individual, their right to self-determination, and the right to make an informed choice is the fundamental principle which must be upheld throughout the research on any participant.
- The rights of each participant to physical and mental integrity, to privacy, and to protection of the data concerning him/her in accordance with Data Protection Act 1998 are safeguarded.

In INCLUDE, GCP was used to train the three researchers in the basics of research governance.

The Data Protection Act (1998) guidelines ensure information about the participant is:

- Used fairly and lawfully.
- Used for limited, specifically stated purposes.
- Used in a way that is adequate, relevant, and not excessive.
- Accurate.
- Kept for no longer than is absolutely necessary.

- Handled according to people's data protection rights.
- Kept safe and secure.
- Not transferred outside the UK without adequate protection.

The Data Protection Act was used in INCLUDE to securely store data, store consent recordings, and store audio recordings of the assessments.

Capacity to give informed consent

- Capacity must be assessed in terms of a person's ability to make a decision at the point at which it is required.
- The Mental Capacity Act (2005) states that: "A person must be assumed to have capacity unless it is established that they lack capacity".

As capacity to give consent was the only inclusion criterion, it was important for the researchers to understand what was required to assess capacity. This was covered in detail during researcher training.

4.3 Structured interviews

4.3.1 Structured interviews

The structured interviews were designed to gather as much relevant information as possible about how the COVID-19 pandemic and concomitant restrictions had or had not affected IDEAL participants while limiting the burden on participants. To achieve this, in many cases single items from measures used in IDEAL were selected. Different versions of the structured interviews were prepared for people with dementia and carers. The structured interviews included brief measures and items from validated scales used in the IDEAL study and bespoke questions focusing on experiences during the pandemic, with additional open-ended questions offering opportunities to expand on specific responses. To enable some comparison of experiences during the pandemic against data from a wider sample of the older population, two questions were included from the English Longitudinal Study of Ageing COVID-19 Sub-Study. The English Longitudinal Study of Ageing COVID-19 Sub-Study Wave 2 was conducted during November and December 2020, which is approximately halfway through data collection for INCLUDE, therefore English Longitudinal Study of Ageing COVID-19 Sub-Study Wave 2 data are the most appropriate for comparison with INCLUDE data.

For people with dementia and carers, demographic information was available from previously collected IDEAL data. These data are included in the datasets.

For people with dementia, interviews began with questions about health and healthcare during the pandemic, and subsequent sections covered perceptions of social connection and relationships, psychological health, ability to manage everyday life, and overall perceptions of their capability to 'live well.' The Hong Kong [1]

version of the 5-minute MoCA, suitable for remote administration, was administered to assess cognition. In IDEAL, the MMSE was used on entry to the study and at subsequent timepoints to monitor cognitive changes. The Hong Kong version of the 5-minute MoCA was used instead of the North American version so that total MoCA scores could be converted to estimated MMSE scores using the conversion tables reported in Wong et al., (2018) [2].

In the first half of their interview, carers were asked or self-completed questions about themselves and their own experiences and in the second half they provided information about the person with dementia. The questions covered health, social networks, psychological well-being, and caregiving experiences.

4.3.2 Procedure

Trained interviewers contacted potential participants to discuss the study by telephone or email according to individual preferences. Where people could not be contacted by telephone or email, towards the end of the study an invitation letter was sent to the last known address containing a reply slip and stamped addressed envelope as well as details of how to contact the team by telephone or email.

In initial conversations with participants, interviewers provided information about the study and answered questions to ensure that participants could make an informed decision about whether to participate. The participant information sheets were either sent to participants via email, where available, or were read out verbatim over the telephone. Informed consent was taken in a follow-up call except where there was any indication that the participant lacked capacity to consent. Each consent was audio-recorded and the researcher taking consent also completed a digital consent form. All participants were asked if they wanted a printed copy of their consent form. Those who did were sent these in the post. The structured interviews for people with dementia who consented to participate were then conducted over the telephone or online via platforms such as Zoom or Microsoft Teams according to participant preference; details of the chosen method of assessment (telephone or videoconference) are included in the datasets. Each interview was audio-recorded. Carers were given the additional option of self-completing the survey online and in these instances an audio-recording was not obtained. Interviews could be undertaken in a single session or over several shorter sessions depending on the wishes of each participant. Protocols were in place to ensure that appropriate responses were used should a participant become distressed during the interview, and appropriate action would be taken should significant concerns arise about the welfare of a participant.

4.4 Semi-structured interviews

The option to take part in an additional in-depth semi-structured interview was presented to participants in the following section of the participant information sheet: “We might ask you to talk to a researcher again a few weeks later and tell us more about your experiences. This would take up to 30 minutes and would be audio-recorded and later written out in full". The carer information sheet was similarly worded.

4.4.1 Identification of participants

The three researchers who conducted the quantitative assessments identified people who were both willing and able to participate in an in-depth semi-structured interview, ensuring that people with different demographic characteristics and experiences of the COVID-19 pandemic were captured. Participants who had previously undertaken an in-depth interview as part of the IDEAL COVID-19 Dementia Initiative (IDEAL-CDI) study [3, 4] were not approached; for more information about IDEAL-CDI please see O'Rourke et al (2021) [3, 4]. The contact details of the participants that had agreed to be approached about taking part in semi-structured interviews were passed on to four researchers, experienced in qualitative research, who went on to conduct these in-depth interviews. Overall, 51 semi-structured interviews were conducted with 36 participants: 19 people with dementia and 17 carers.

4.4.2 Procedure

There were three sets of semi-structured interviews.

The first set of interviews was conducted between November and December 2020. Out of the sub-sample available at the time, the qualitative researchers attempted to contact participants to determine whether they were still eligible (e.g., still living in the community) and interested in participating in an in-depth interview. Eighteen interviews were conducted representing 21 participants; 8 people with dementia and 7 carers were interviewed individually and 3 were joint interviews, i.e., the person with dementia and carer were interviewed together. The consent process was covered by the researchers conducting the quantitative assessments as described above, but capacity was assessed again prior to each semi-structured interview, and information regarding the study was repeated with process consent undertaken before, during, and after the interviews.

The second set of interviews was conducted between January and May 2021. Out of the original sub-sample not interviewed in the first round of interviews, 10 people with dementia and 12 carers were identified and subsequently contacted. Fourteen interviews were conducted representing 15 participants: 7 people with dementia and 6 carers were interviewed individually, and 1 was a joint interview. Similar to the first set of interviews, participants were fully briefed on the study and process consent was undertaken.

The third set of interviews was conducted between December 2021 and January 2022; this was made possible by a three-month extension to INCLUDE running until March 31st, 2022. For these interviews, participants had previously been interviewed either for the IDEAL-CDI study or one of the two sets of earlier INCLUDE in-depth interviews. Seventeen people with dementia and 15 carers were contacted to determine eligibility, interest, and availability to take part in a second in-depth interview. A total of 9 people with dementia and 10 carers were interviewed. Of the people with dementia interviewed in this third set, 6 participants were from INCLUDE set 1 interviews, 2 from INCLUDE set 2 interviews, and 1 from IDEAL-CDI. Of the carers interviewed in this third set, 6 participants were from INCLUDE set 1 interviews, 3 from

INCLUDE set 2 interviews, and 1 from IDEAL-CDI. No dyadic interviews were conducted. For this round of interviews, capacity to consent was assessed, study information was provided, and new verbal consent was recorded.

4.4.3 Topic guide

The same topic guide was used for each set of interviews. The questions were open-ended to allow for flexibility, for example to reflect the COVID-19 social restrictions at the time of the interview. Specifically, more personal prompts were included in the third set of interviews as a source of reflection on and triangulation with previous interviews.

4.4.4 Participants

The characteristics of the participants for each set of interviews are provided in Table 4.

Table 4: Demographic characteristics of people with dementia and carers who took part in the three sets of semi-structured interviews

	First Set		Second Set		Third Set	
	People with dementia	**Carers**	**People with dementia**	**Carers**	**People with dementia**	**Carers**
Number of participants	11	10	8	7	9	10
Interview length (minutes)						
Individual interviews	24 - 53	25 - 53	32 - 79	39 - 74	23 - 45	28 - 61
Joint interviews	23 - 60	23 - 60	41	41	-	-
Sex						
Women	3	5	5	5	4	5
Men	8	5	3	2	5	5
Age distribution						
< 65	2	1	4	5	3	3
65 – 69	4	1	1	-	2	-
70 – 74	2	7	2	-	1	5
75 – 79	2	1	-	-	1	1
80+	1	-	1	2	2	1
Diagnosis type						
Alzheimer's disease (AD)	6	6	3	4	6	4
Vascular dementia	1	-	2	-	-	1
Mixed AD and vascular dementia	1	-	2	1	1	-
Frontotemporal dementia	3	4	1	1	2	4
Other	-	-	-	1	-	1
Living situation						
Living with others	7	-	5	-	5	-
Living alone	4	-	3	-	4	-
Relationship with primary carer						
Spouse/partner	7	9	3	5	4	10
Other family/friend	-	1	1	1	-	-
No carer in study	4	-	4	-	5	-

4.5 Data cleaning for the archive

As the study is archived with the UK Data Service for re-use, extensive data cleaning was undertaken to ensure participants and any third parties could not be re-identified. The CRFs had many free-text fields where names, post codes, or other directly identifiable information were sometimes found. More commonly, indirect identifiers were sometimes found, such as age, workplace, occupation, etc. Data cleaning either completely removed these identifiers or aggregated them into groups, such as “adult child” for son/daughter, or “other health condition” for epilepsy or any health conditions other than dementia. This was done by University of Exeter researchers under the instruction of their University research governance officers.

For variables deemed high-risk for re-identification, for example date of birth, derived variables were produced. Derived variable specifications are provided in Data documents.

5. Using the data

5.1 SPSS data files

5.1.1 Information about data files

SN 855800 release comprises two files in the SPSS (.sav) format, distributed by UK Data Service. Researchers without an SPSS licence should be able to use the open-source software programme R to access the datasets. However, some variables and variable labels might get truncated.

The dataset filenames are composed of the following identifiers: UK Data Service study number, Study name, cohort, and version number. See Figure 1.

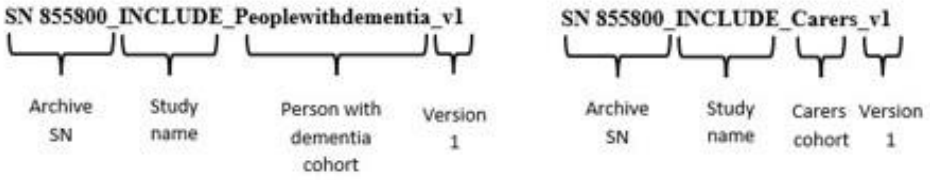

Figure 1: Dataset filenames

5.1.2 Variable naming and labelling conventions

Variable labels are generally composed of the following identifiers: the participant cohort and survey part (where the question is found); the question number; and the question option (if applicable). See Figure 2 for examples. For some of the demographic questions in the people with dementia dataset, the question itself is used for the variable label, e.g., Sex_Prtcpnt_. Some of the questions asking to specify "other" information end "_oth".

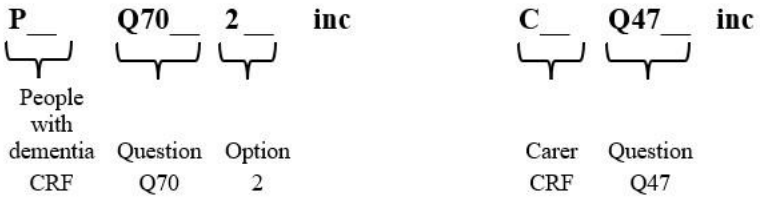

Figure 2: Variable naming conventions

5.1.3 Learning about the study variables

There are multiple documents that can be used with the study datasets to plan analyses. These include the archived CRFs in Interview documents; the measures, variable lists, and data dictionaries in Data documents; and variable view in the archive dataset SPSS files themselves.

Many of the non-derived variables can be learned about directly from the CRFs, which present a full description of what was asked and where prompts were used to help participants answer. One way to do this is to search for the desired variable label in the survey .pdf using the Find command. An example from the survey can be seen in Figure 3.

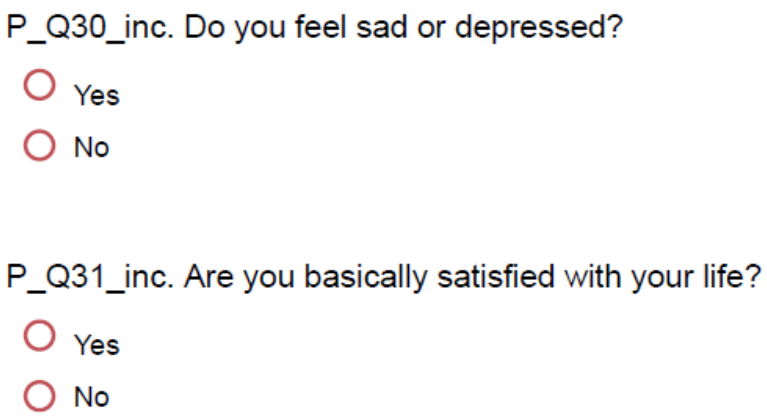

Figure 3: Example of how the variable names align with the questions in the survey

Question numbering in the datasets is the same as the question numbering in the pdf files containing the CRFs for all questions with two exceptions: medication in both CRFs and animal fluency in the person with dementia CRF. In Figure 4, asterisks have been used in the pdf CRFs for the medication responses. The medication questions were split into three sub-questions, name of medication, dosage, and frequency, and it was not possible to amend the pdf CRF to indicate this. In the dataset, the numbering convention is as follows: Meds_1, and all variables with Meds_1 in the variable name, relates to the first named medication, Meds_2, and all variables with Meds_2 in the variable name, relates to the second named medication and so on. Meds_1_1 is the name of first named medication, Meds_2_1 is the name of second named medication and so on. Meds_1_2 is the dosage of the first named medication, and Meds_2_2 is the dosage of the second named medication and so on. Meds_1_3 is the frequency (i.e., how often the medication is taken) of the first named medication, and Meds_2_3 is the frequency of the second named medication and so on; frequency of medication was a dropdown menu whereas named medication and dosage was free text.

Please note, in the pdf, the number of medications could go up to a possible 42 different medications. However, the datasets stop at the maximum number of medications given during the interviews, i.e., the person with dementia dataset includes 19 different medications. Therefore, the variables P_Q107_Meds_20_1_inc to P_Q107_Meds_42_3_inc do not exist in the dataset for people with dementia; similarly, the carer dataset includes 28 different medications, therefore the variables C_Q130_Meds_29_1_inc to C_Q130_Meds_42_3_inc do not exist in the carer dataset.

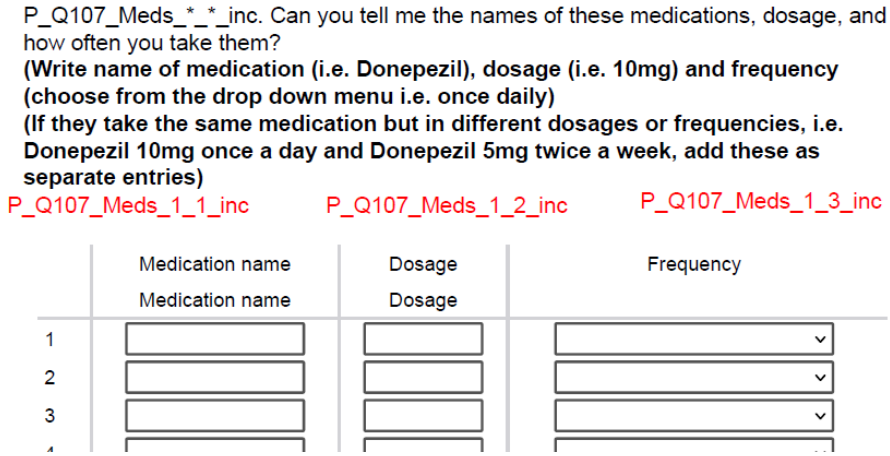

Figure 4: Question numbering for medication questions

For animal fluency, asterisks are also used in the question numbering in the pdf file containing the CRF for a similar reason. In the dataset each animal or word given by a participant is entered into its own column. Therefore, P_Q111_1_R indicates the first animal or word given on the task, P_Q111_2_R indicates the second animal or word given on the task, and so on up to P_Q111_32_R; this is the final column for animal fluency as no participant said more than 32 animals or words in the time allowed. The letter R in the variable name indicates Response.

Analysts are advised to carefully read the SPSS variable view description for desired variables to ensure the questions they are analysing are what they expect.

5.1.4 Variable values

The SPSS variable view gives a list of the value labels for each question. These can also be found in the data dictionaries.

It may appear that some variables have a lot of missing data. However, skip conditions were used to reduce the time taken to conduct interviews where questions were not applicable; for example, if a person said that they had no access to the internet and did not use the internet there are no responses for this participant for subsequent questions about different ways of using the internet. Another example is for the question: "P_Q78_inc. Do you have a garden or outside area that you can spend time in?"; this question was only asked if the answer 'yes' was given to the earlier question "P_Q75_inc. During the past 3 days have you been to an area outside your home or place of residence, such as a garden, yard, driveway or parking space?"

5.1.5 Derived variables

Derived variables were computed by the co-ordinating centre using third-party software. In the archive datasets, all derived variables were created and computed post-field for the purpose of analysis. Some of the derived variables were created to reduce the risk of re-identification, such as the Age Groups and Nomenclature of Territorial Units for Statistics (NUTS) level 1 classification variables. Derived variables are grouped together at the beginning of the datasets to be easily identified by their position in the files. A

list of the derived variables and how they were computed is found in Data documents. In nearly all cases, derived variables were created from data collected as part of IDEAL and/or IDEAL-2.

5.1.6 Combining datasets

Apart from P_ID, all variables include identifiers for the cohort (either P or C). This allows simple identification of which dataset a variable is taken from when combining variables.

P_IDs are unique identifiers attributed to a person with dementia. In carer datasets, the P_ID links the carer with the corresponding person with dementia.

It is also possible that one member of the study dyad (either the person with dementia or the carer) did not take part when the other member of the study dyad did. This should be considered when conducting comparative analyses. A variable indicating whether there was a dyad taking part or not is included in both datasets (P_Dyad_inc or C_Dyad_inc).

5.2 Semi-structured interview transcripts

5.2.1 Information about interview transcripts

There are 51 semi-structured interviews, each in a separate pdf document. The transcript filenames are composed of the following identifiers: UK Data Service study number, Study name, Interview wave, and Transcript number. See Figure 5.

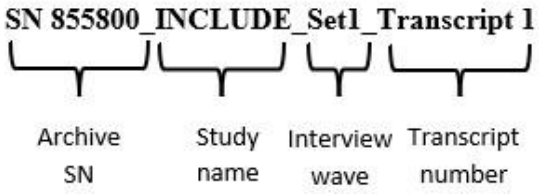

Figure 5: Semi-structured interview transcript filename

The interview transcripts are organised into three folders:

1 – Interviews with people with dementia interviews, containing 24 interview transcripts numbered 1 to 24.

2 – Interviews with carers, containing 23 interview transcripts numbered 25 to 47.

3 - Joint interviews, containing 4 interview transcripts numbered 48 to 51.

5.2.2 Structuring of the interview transcripts

Each interview transcript has the participant study ID number at the start of the document, along with an indication of the interview type - whether it is with a person with dementia, carer, or dyad (person with dementia and carer together). To identify who is speaking, "I" denotes the interviewer and "P" the interviewee. In the joint interviews, "P1" is used for the carer and "P2" for the person with dementia.

5.3 Requesting sensitive data

If you have a research objective that requires sensitive data, please make a request to the IDEAL team by email: IDEAL@exeter.ac.uk.

5.4 Ethical approval

INCLUDE was approved by Wales Research Ethics Committee 5 as an amendment to IDEAL-2 for England and Wales (18/WS/0111 AM12). IDEAL was approved by Wales Research Ethics Committee 5 (reference 13/WA/0405) and IDEAL-2 by Wales Research Ethics Committee 5 (reference 18/WS/0111) and Scotland A Research Ethics Committee (reference 18/SS/0037). IDEAL and IDEAL-2 are registered with the UK Clinical Research Network (UKCRN), numbers 16593 and 37955, respectively.

6. Citing the data

When publishing results from the study data, the following citation must be used:

University of Exeter, REACH; Clare, L. (CI), Victor, C., Matthews, F.E., Quinn, C., Hillman, A., Burns, A., Allan, L., Litherland, R., Martyr, A., Collins, R., & Pentecost, C. (2020-2022). *Identifying and mitigating the individual and dyadic impact of COVID-19 and life under physical distancing on people with dementia and carers: an additional COVID-19 specific module for the IDEAL-2 study (INCLUDE)*. [data collection]. UK Data Service. SN: 855800. doi: 10.5255/UKDA-SN-855800

7. Acknowledgements

‘Identifying and mitigating the individual and dyadic impact of COVID19 and life under physical distancing on people with dementia and carers (INCLUDE)’ was funded by the Economic and Social Research Council (ESRC) through grant ES/V004964/1. Investigators: Clare, L., Victor, C., Matthews, F., Quinn, C., Hillman, A., Burns, A., Allan, L., Litherland, R., Martyr, A., Collins, R., & Pentecost, C. ESRC is part of UK Research and Innovation (UKRI). The views expressed in this report are those of the author(s) and not necessarily those of the ESRC or UKRI. The support of ESRC is gratefully acknowledged. We thank the members of the ALWAYS group, the members of the IDEAL Project Advisory Group and its Chair, Dr Nori Graham, the local PIs and their teams at the study sites, and Dr Laura Gamble for statistical support, Anna Hunt, Eleanor Dawson, and Sophie Parker for research assistance, Dr Serena Sabatini for research support, Dr Sally Stapley for conducting semi-structured interviews, Madhumathi Ravi for data management support, Dr Catherine Charlwood for knowledge transfer support, Sarah Vinnels for administrative assistance, and all the people with dementia and carers participating in the study.

The IDEAL Programme team would like to acknowledge the Centre of Excellence funding provided by Alzheimer’s Society to support further research with the IDEAL cohort following completion of the original IDEAL study: ‘Improving the experience of Dementia and Enhancing Active Life: a longitudinal perspective on living well with dementia. The IDEAL-2 study’, grant number 348, AS-PR2-16-001. Investigators: Clare, L., Jones, I.R., Victor, C., Ballard, C., Hillman, A., Hindle, J.V., Hughes, J., Jones, R.W., Knapp, M., Litherland, R., Martyr, A., Matthews, F.E., Morris, R.G., Nelis, S.M., Quinn, C., Rusted, J. This research is supported by the National Institute for Health and Care Research (NIHR) Applied Research Collaboration South-West Peninsula (PenARC). The views expressed in this report are those of the author(s) and not necessarily those of the NIHR or Alzheimer’s Society. The support of NIHR and Alzheimer’s Society is gratefully acknowledged.

8. Publications

Comprehensive and regularly updated links to publications, presentations, blogs and media, and infographics can be found on the IDEAL programme website: http://www.idealproject.org.uk/

A dementia toolkit was developed as part of the INCLUDE study and it can be found here: https://livingwithdementiatoolkit.org.uk/

For the purposes of this User guide, a list of publications in chronological order taken from the website in June 2022 is as follows:

8.1 Published articles

Clare, L., Martyr, A., Gamble, L. D., Pentecost, C., Collins, R., Dawson, E., Hunt, A., Parker, S., Allan, L., Burns, A., Hillman, A., Litherland, R., Quinn, C., Matthews, F. E., & Victor, C. (2022). Impact of COVID-19 on 'living well' with mild-to-moderate dementia in the community: findings from the IDEAL cohort. *Journal of Alzheimer's Disease*, *85*(2), 925-940. https://doi.org/10.3233/JAD-215095

Sabatini, S., Bennett, H. Q., Martyr, A., Collins, R., Gamble, L. D., Matthews, F. E., Pentecost, C., Dawson, E., Hunt, A., Parker, S., Allan, L., Burns, A., Litherland, R., Quinn, C., & Clare, L. (2022). Minimal impact of COVID-19 on the mental health and well-being of people living with dementia: analysis on matched longitudinal data from the IDEAL study. *Frontiers in Psychiatry*, *13*, 849808. https://doi.org/10.3389/fpsyt.2022.849808

Quinn, C., Gamble, L. D., Parker, S., Martyr, A., Collins, R., Victor, C., Dawson, E., Hunt, A., Pentecost, C., Allan, L., & Clare, L. (2022). Impact of COVID-19 on carers of people with dementia in the community: findings from the British IDEAL cohort. *International Journal of Geriatric Psychiatry*, *37*(5). https://doi.org/10.1002/gps.5708

Gamble, L. D., Parker, S., Quinn, C., Bennett, H. Q., Martyr, A., Sabatini, S., Pentecost, C., Collins, R., Dawson, E., Hunt, A., Allan, L., Burns, A., Litherland, R., Victor, C., Matthews, F. E., & Clare, L. (2022). A comparison of well-being of carers of people with dementia and their ability to manage before and during the COVID-19 pandemic: findings from the IDEAL study. *Journal of Alzheimer's Disease*. https://doi.org/10.3233/JAD-220221

Pentecost, C., Collins, R., Stapley, S., Victor, C., Quinn, C., Hillman, A., Litherland, R., Allan, L., & Clare, L. (2022). Effects of social restrictions on people with dementia and carers during the pre-vaccine phase of the COVID-19 pandemic: experiences of IDEAL cohort participants. *Health & Social Care in the Community*. https://doi.org/10.1111/hsc.13863

9. References

[1] Wong, A., Xiong, Y. Y., Kwan, P. W., Chan, A. Y., Lam, W. W., Wang, K., Chu, W. C., Nyenhuis, D. L., Nasreddine, Z., Wong, L. K., & Mok, V. C. (2009). The validity, reliability and clinical utility of the Hong Kong Montreal Cognitive Assessment (HK-MoCA) in patients with cerebral small vessel disease. *Dementia and Geriatric Cognitive Disorders*, *28*(1), 81-87. https://doi.org/10.1159/000232589

[2] Wong, A., Black, S. E., Yiu, S. Y. P., Au, L. W. C., Lau, A. Y. L., Soo, Y. O. Y., Chan, A. Y. Y., Leung, T. W. H., Wong, L. K. S., Kwok, T. C. Y., Cheung, T. C. K., Leung, K. T., Lam, B. Y. K., Kwan, J. S. K., & Mok, V. C. T. (2018). Converting MMSE to MoCA and MoCA 5-minute protocol in an educationally heterogeneous sample with stroke or transient ischemic attack. *International Journal of Geriatric Psychiatry*, *33*(5), 729-734. https://doi.org/10.1002/gps.4846

[3] O'Rourke, G., Pentecost, C., van den Heuvel, E., Victor, C., Quinn, C., Hillman, A., Litherland, R., & Clare, L. (2021). Living with dementia during the COVID-19 pandemic: coping and support needs of community-dwelling people with dementia and their family carers. Research findings from the IDEAL COVID-19 Dementia Initiative (IDEAL-CDI). Older People and Frailty Policy Research Group. https://documents.manchester.ac.uk/display.aspx?DocID=54837

[4] O'Rourke, G., Pentecost, C., van den Heuvel, E. A., Victor, C., Quinn, C., Hillman, A., Litherland, R., & Clare, L. (2021). Living with dementia under COVID-19 restrictions: coping and support needs among people with dementia and carers from the IDEAL cohort. *Ageing & Society*. https://doi.org/10.1017/S0144686X21001719