Identifying and mitigating the individual and dyadic impact of COVID-19 and life under physical distancing on people with dementia and carers: evidence from the IDEAL-2 cohort (INCLUDE)

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

PROTOCOL

GENERAL INFORMATION

Full title of the study

Identifying and mitigating the individual and dyadic impact of COVID-19 and life under physical distancing on people with dementia and carers: evidence from the IDEAL cohort

Short study title

Living well and enhancing active life: the impact of COVID-19

Acronym

INCLUDE

Protocol version number and date

Version 1 dated 16/06/2020

This protocol has regard for HRA guidance.

Research Reference numbers

INCLUDE operates under the IDEAL-2 IRAS number, Sponsor's number and UKCRN registration as an additional component of the IDEAL-2 study, but is separately funded.

IDEAL-2 details:

IRAS Number: 235712
Sponsor's number: 1718/08
Funder's number: 348 (AS-PR2-16-001)
UKCRN registration: 37955

INCLUDE details:

INCLUDE funder's number: ES/V004964/1

Duration of funding period

Start date: 18/06/2020

End date: 17/12/2021

Signature Page

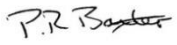
The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

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 Sponsor

Signature:

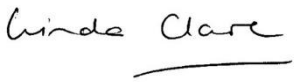


Date: 09/07/2020

Name: Ms Pam Baxter

Position: Senior Research Governance Officer, University of Exeter

Chief Investigator

Signature:  Date: 09/09/2020

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PROTOCOL AMENDMENT HISTORY

Author	**Protocol version**	**Date**	**Details**
Professor Linda Clare	1.0	09/07/2020	This is the original version of the protocol.

LIST OF CONTENTS

LIST OF ABBREVIATIONS

ALWAYs	Action on Living Well: Asking You – the patient and public involvement (PPI) group of people with dementia and carers engaged in the IDEAL programme
COVID-19	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)
IDEAL	Improving the experience of Dementia and Enhancing Active Life – this term is used to refer to the overall research programme to which INCLUDE belongs, and more specifically to the first phase of the programme that included the first three waves of data collection from the IDEAL cohort
IDEAL-2	The specific term used to refer to the second phase of the IDEAL programme, covering waves 4, 5 and 6 of data collection from the IDEAL cohort
LILAC	Living Well Alongside Coronavirus – the toolkit of resources to be developed in the INCLUDE study
SPSS	IBM SPSS Statistics – a statistical data analysis software package
T4, T5, T6	Timepoints 4, 5 and 6 – referring to the three waves of data collection from the IDEAL cohort in IDEAL-2

PROJECT SUMMARY

Title

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

Short title

Living well and enhancing active life: the impact of COVID-19

Background

As COVID-19 becomes endemic, with physical distancing likely to continue for at least two years, our approach to delivering high-quality care and support for people affected by dementia must change. The IDEAL programme offers a developing evidence-based theoretical framework outlining key individual and dyadic influences on 'living well' with dementia, which highlights in particular the importance of social and psychological resources. We will use this framework to examine the impact of COVID-19.

Aims

INCLUDE aims to identify the impact of COVID-19 and resulting physical distancing measures on people with dementia and family carers. By linking post-COVID responses to pre-COVID data we will identify the impact of COVID-19 on trajectories of symptoms and well-being. We will use our findings to develop resources to support people with dementia and carers to 'live well' alongside endemic COVID-19.

Design

INCLUDE is a mixed-methods cross-sectional observational study embedded in, and forming a discrete component of, the ongoing longitudinal research with the IDEAL cohort. INCLUDE will add a COVID-19-specific data-collection module to the nationwide IDEAL-2 study. Participants will complete questionnaires and respond to open-ended questions in a structured interview, and a sub-set will additionally complete a semi-structured interview.

Study participants and planned recruitment

We will invite people with dementia and carers participating in the IDEAL-2 study to take part in INCLUDE. We expect up to 600 respondents in total, 300 people with dementia and 300 carers (hence 300 dyads), to complete the core module. Up to 100 participants (50 dyads) will contribute further in-depth interviews to augment the survey data. We will use the resulting evidence to refine our theoretical framework and, based on this, to co-produce the Living Well Alongside Coronavirus (LILAC) toolkit, a set of resources to support the social, mental and physical health and relationships of people affected by dementia and provide guidance for health, social care and voluntary sector staff.

Study period

INCLUDE is funded for 18 months starting on 18th June 2020.

Key words

Quality of life, satisfaction with life, well-being, living well, Alzheimer's disease

ROLES AND RESPONSIBILITIES

Funding and support in kind

INCLUDE is 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.

Support in kind is provided by Alzheimer's Society as project partner. Alzheimer's Society is represented by Colin Capper, Head of Research Development and Evaluation.

Role of study sponsor

The University of Exeter is the sponsor with legal responsibility for the research integrity of the study. This role will be delegated to the Chief Investigator.

The sponsor plays no role in the design of the study, and will have no role in data analysis or interpretation, or writing up of findings of the study.

The study sponsor will ensure that the research team has access to resources and support to deliver the research as proposed and that responsibilities for management, monitoring and reporting of the research are in place prior to the study commencing. The sponsor will ensure that there is agreement on recording, reporting and reviewing significant developments as the research proceeds and approve any modifications to design, obtaining requisite regulatory authority.

The sponsor will assume responsibility for operating the management and monitoring systems of the research.

Role of funder

The funding review process provided feedback on the design of the programme. The funder plays no further role in the design of this individual study and will have no role in data analysis or interpretation, or writing up of findings of the study. The funder will receive copies of study outputs, but has no role in the decision to submit for publication.

Role of Exeter CTU

The IDEAL-2 data manager at Exeter CTU will provide the INCLUDE programme manager with contact information for IDEAL-2 participants who are still in the study.

Flow chart

A flow chart can be found in Appendix 1.

Timelines

Charts summarising INCLUDE study timelines and indicating how these timelines relate to IDEAL programme timelines can be found in Appendix 2.

BACKGROUND AND RATIONALE

Background

Physical distancing measures brought in to contain the spread of COVID-19 disproportionately affect particular groups. The older population, which is subject to more rigorous guidance, includes over 850,000 people with dementia, two-thirds of whom live in the community supported primarily by family carers. Personal contact is key to well-being for people with dementia, while carers are at high risk of social isolation and loneliness. People affected by dementia are therefore especially vulnerable to the impact of physical distancing and self-isolation on social, mental and physical health and relationships.

The acute phase of the pandemic has necessitated rapid changes to individual lifestyles, community cohesion, and health and social care delivery. The disadvantages people affected by dementia experience have already combined to create additional vulnerabilities with significant impacts. With social restrictions continuing for an extended period, people affected by dementia now risk being 'left behind' as the rest of the population adapts, creating increasing pressures on relationships within caregiving dyads. This risk is exacerbated by the shift to online provision, given that a high proportion of people with dementia in the UK do not use the internet or own smartphones.

Rationale

It is important to understand and address the impact on people affected by dementia of both the acute phase response and the ongoing social restrictions as COVID-19 becomes endemic, and to understand how this impact adds to the pre-existing challenges of living with dementia or caring for a person with dementia. This presents an opportunity to build solutions that mitigate the negative consequences, by harnessing the resources people affected by dementia have to offer, mobilising communities to support them more effectively, and optimising delivery of health and social care services.

Theoretical framework

We will use the developing IDEAL theoretical framework outlining key influences on 'living well' with dementia, which highlights in particular the importance of social and psychological resources, as a basis for identifying the impact of COVID-19 on individuals, and for understanding how a given impact on the person with dementia affects the carer and vice versa.

'Living well' with a long-term condition has been defined as 'the best achievable state of health that encompasses all dimensions of physical, mental and social well-being', and described as having a 'unique personal meaning which is defined by a self-perceived level of comfort, function and contentment with life' and as being 'shaped by the physical, social and cultural surroundings, and by the effects not only on the affected individual but also on family members, friends and caregivers' (Institute of Medicine, 2012, p.32). In IDEAL, 'living well' is conceptualised and measured as a combination of quality of life, satisfaction with life, and well-being. Although there is some measurement overlap between these three constructs, they do capture distinct aspects of people's experience, and taken together may provide a more comprehensive picture (Clare et al., 2014).

Dementia poses particular challenges for 'living well' because of the nature of the symptoms and their secondary effects such as anxiety or loss of confidence, because it is a stigmatised condition, and because communities are not inclusive and environments are not well-adapted. This points to the relevance of a biopsychosocial model of disability which acknowledges the impact of both

internal and external factors on activity and participation (World Health Organization, 2002). This is consistent with the dialectical model of dementia put forward by Kitwood (1998) which emphasises the role of social influences, and in particular the negative effects of a 'malignant social psychology', on the potential for people with dementia to 'live well' with the condition. There is a well-developed theoretical model that attempts to account for differing outcomes among family carers of people with dementia, the stress process model (Pearlin et al., 1990), but this has been criticised as further developments indicate the need for two-factor models addressing positive as well as negative aspects of caregiving (Lawton, 1991; Kramer, 1997). Equivalent explanatory models are less evident in relation to people with dementia, although it has been proposed that the stress process model can be equally applied to them (Judge et al., 2010).

Research exploring the factors that account for differences in outcome among people with dementia or family carers has tended to examine associations of specific factors with indices of 'living well', primarily quality of life. In regard to people with dementia, our recent systematic review and meta-analysis (Martyr et al., 2018), which included information from 37,369 people with dementia described in 272 journal articles reporting on 198 individual studies, demonstrated that numerous factors are significantly associated with quality of life but often with small or negligible effect sizes. Good relationships, better functional ability and more social engagement were moderately associated with better quality of life, while depression, neuropsychiatric symptoms and poor physical health, and lower carer well-being, were moderately associated with poorer quality of life. There was no conclusive evidence about baseline predictors of later quality of life. In regard to carers, a narrative systematic review (Farina et al., 2017) found that relationship quality, physical and mental health, positive emotional reactions, self-efficacy, independence and higher income were associated with better quality of life, as was better quality of life in the person with dementia, while depression, anxiety, burnout and stress were associated with poorer quality of life, along with unmet needs, functional impairment and lack of awareness on the part of the person with dementia. While these reviews provide evidence about factors that may influence outcomes, and point to the relevance of social, emotional and psychological factors, there is still a need for a coherent conceptual framework that demonstrates not only which factors are relevant but how they operate and interact to result in differing outcomes.

The IDEAL programme was designed from a social science perspective to explore and model personal, social and environmental influences on capability to 'live well' with dementia for both people with dementia and carers, cross-sectionally and longitudinally (Clare et al., 2014; Silarova et al., 2018). The initial conceptual framework focused on six life domains common to both people with dementia and carers, with one additional domain for carers. The six common domains were: psychological characteristics and psychological health; physical fitness and health; social capitals, assets and resources; social situation; relationships; and managing everyday life with dementia. For carers, the domain of experiencing caregiving was added.

Comprehensive statistical modelling of cross-sectional data from participants with dementia indicated that all domains except relationships were significantly associated with 'living well', but when modelled together, psychological characteristics and health was the only domain independently associated with 'living well' (Clare et al., 2019a). Similarly, modelling of cross-sectional data from carers indicated that all domains except relationships and managing everyday life with dementia were significantly associated with 'living well' but when domains were modelled together, psychological characteristics and health dominated (Clare et al., 2019b).

This, together with further detailed within-domain analyses (Lamont et al., 2019, 2020; Martyr et al., 2019; Nelis et al., 2019; Quinn et al., 2019a, 2019b, 2020; Victor et al., 2020a, 2020b; Wu et al., 2018a, 2018b) and application of actor-partner independence models exploring reciprocal associations within dyads (Wu et al., 2019; Rippon et al., 2019), allowed us to develop initial theoretical models explaining differences in 'living well' outcomes for people with dementia and carers, showing that the psychological domain is the dominant vehicle through which the associations of other domains with 'living well' operate, indicating which factors within each domain are and are not associated with 'living well', and incorporating partner effects. While a few of the included factors, such as personality traits or type of dementia, are stable, many are potentially modifiable. These include psychological (depression, loneliness, self-efficacy, stigma), social (social isolation, cultural capital, neighbourhood characteristics), and physical (subjective health, physical activity) factors.

Initial longitudinal analyses show that social isolation and loneliness at baseline contribute to poorer quality of life, satisfaction with life and well-being 12 and 24 months later. For people with young-onset dementia, social isolation is also linked with a more rapid decline in functional ability over time.

The period of lockdown and subsequent ongoing social restrictions and physical distancing due to the COVID-19 pandemic provides a natural experiment in which necessary and universal modifications to people's circumstances have in effect manipulated many of the factors identified in IDEAL analyses as associated with capability to 'live well' and with reductions in capability to 'live well' over time. Structural changes have included increased social isolation, limits on physical activity and reduced participation in activities (cultural capital). In some communities, however, neighbourliness has increased, potentially improving reciprocity and trust.

In preparatory work focused on the immediate impact of the pandemic, monitoring of concerns expressed by people with dementia and carers in various networks (e.g. Dementia Diaries https://dementiadiaries.org/ , Alzheimer's Society Dementia Connect https://www.alzheimers.org.uk/dementiaconnect and Innovation Hub https://innovationhub.alzheimers.org.uk/) has indicated a number of dementia-specific effects. For people with dementia, the removal of their usual social activities and means of staying in contact and structuring their time has been devastating and has raised concerns about loss of skills and confidence. Carers who live with the person they support have been unable to take a break or gain respite, and leading to increased feelings of role captivity, social restriction and stress. For both, this has placed greater strain on their relationship. Non-resident carers have been experiencing high levels of anxiety about the safety and well-being of the person they support. Equally, these accounts demonstrate attempts to adapt and find positive meaning in the situation, and to explore possible solutions such as tackling the challenge of learning new ways of staying connected online.

The restrictions resulting from the COVID-19 pandemic directly affect many of the factors emerging from IDEAL analyses as crucial for 'living well' with dementia; these are summarised in Table 1 below. Examining the short- and medium-term impact of COVID-19 and the resulting physical distancing measures on people with dementia and carers who form part of the well-characterised IDEAL cohort will have several benefits:

- Understanding more about the experience of people with dementia and carers, including both the challenges they have faced and the ways in which they have tried to adapt, will make it possible to identify solutions and resources that can help to support people through

the expected longer-term period in which social restrictions and physical distancing remain in place.

- Because data can be analysed in relation to participants' existing survey data, this will make it possible to identify the specific impact of the pandemic on trajectories of dementia-related symptoms, social and psychological well-being and relationship quality, including reciprocal influences within dyads, assessed in many cases over 4 previous time-points.
- The findings will provide robust evidence that can contribute to further developing and refining the theoretical models emerging from the IDEAL cohort study.

Table 1. Factors relevant for 'living well' with dementia likely to have been affected by the restrictions resulting from the COVID-19 pandemic

Domain	**Person with dementia – potentially relevant factors**	**Carer – potentially relevant factors**
Psychological characteristics and health	Optimism, self-esteem, self-efficacy Loneliness, depression, self-discontinuity, perceived stigma	Optimism, self-esteem Loneliness, depression
Social capitals, assets and resources	Social isolation, civic participation, cultural capital (activity participation) Neighbourhood reciprocity and trust	Frequency of social contact, social resources, social isolation, cultural capital (activity participation), civic participation Neighbourhood reciprocity and trust
Social situation	Living situation, perceived social status, area-level deprivation	Perceived social status
Physical fitness and health	Subjective health, physical activity	Subjective health
Managing everyday life with dementia	Functional ability, dependence	Distress at neuropsychiatric symptoms
Relationship	Quality of relationship with carer	Quality of relationship with person with dementia
Experiencing caregiving		Role captivity, social restriction, stress
Partner effects	Carer competence, depression, perceived social restrictions, stress, perceived social status	Person with dementia depression, perceived social status

GOALS AND OBJECTIVES

The goals of INCLUDE are:

- To identify the impact of COVID-19 on people with dementia and carers.
- To understand reciprocal dyadic influences - how a given impact on the person with dementia affects the carer and vice versa.
- To build on this evidence to create resources to support the social, mental and physical health and relationships of community-dwelling people with dementia and their family carers and provide guidance to health, social care and voluntary sector staff.

Objectives

- To fully involve people with dementia and carers throughout the project
- To develop the INCLUDE COVID-19-specific data collection module
- To develop optimised methods for remote data collection
- To maximise participation by potentially-eligible IDEAL-2 study participants
- To describe and analyse quantitative and qualitative data, both independently and in context of participants' previous survey responses
- To provide regular briefings on the emerging findings
- To create a set of evidence-based resources to form the Living Well Alongside Coronavirus (LILAC) toolkit
- To disseminate the LILAC toolkit
- To disseminate the INCLUDE findings through scientific and non-academic channels

INCLUDE will be conducted through three work packages.

WORK PACKAGE 1: DEVELOPING THE INCLUDE DATA MODULE

Timeline: Months 1 - 3

We will develop the INCLUDE data-collection module to gather COVID-specific quantitative and qualitative data from people with dementia and carers, with full involvement of members of the ALWAYs Patient and Public Involvement (PPI) group and project partners Alzheimer's Society and Innovations in Dementia, and carry out the preparatory work needed to set up the study so that data collection can begin.

<u>Developing the data-collection module</u>

To develop the INCLUDE data-collection module we will draw on emerging findings from IDEAL as outlined above, and on the concerns and needs identified through monitoring relevant networks and interviewing people with dementia and carers during the acute phase of the COVID-19 pandemic, as well as on the lived experience of ALWAYs group members. Development will cover three main areas:

- Methods for remote interviewing. We will build on existing work and relevant literature, and on the experience of project partners and ALWAYs group members, to identify effective ways of collecting data through telephone and online interviews, and establish a menu of options from which participants can choose.
- Structured interviews. We expect that the structured interviews will include brief standardised questionnaires, specially-tailored questions, and open-ended questions. The standardised questionnaires covering key areas such as mental health and well-being will include measures previously used in IDEAL and new measures to address areas that are

relevant but not covered in IDEAL, such as anxiety. The specially-tailored questions will address specific features of the current situation; we have noted that the English Longitudinal Study of Ageing has received funding for a COVID-specific survey and we will explore the possibility of including a small number of questions from this to allow benchmarking against the general older population. Open-ended questions were introduced in IDEAL at the suggestion of the ALWAYs group and have proven to be a valuable method of eliciting relevant aspects of participants' experiences and views.

- Semi-structured interviews. A sub-set of participants will also have in-depth semi-structured interviews, and we will develop a detailed interview protocol drawing on a similar protocol devised to capture the experiences of people with dementia and carers during the acute phase of the pandemic. We will identify criteria for purposive sampling to ensure that we include participants from the most vulnerable groups; for example based on existing survey data we can identify those who do not access the internet (over 80% of people with dementia in IDEAL), people with dementia living alone (18% of people with dementia in IDEAL), and those who are lonely (35% of people with dementia and 61% of carers) and/or socially isolated (35% of people with dementia and 18% of carers).

Study set-up

During this period we will prepare for the start of data collection, ensure staff are in place to conduct study activities, and initiate the working groups that will support data analysis.

Approval for the INCLUDE module will be sought as an amendment to existing approvals, allowing work to proceed quickly. Development of the interview schedules will be prioritised so that they can be submitted with the amendment by the end of Month 1.

We will put in place our plans for data capture and data management, and prepare a detailed statistical analysis plan outlining the proposed analyses for the quantitative data.

WORK PACKAGE 2: DATA COLLECTION AND ANALYSIS

Timeline: Months 4 – 18, covering data collection Months 4 – 10; data analysis Months 5 – 16; and data archiving Months 16 – 18.

DESIGN

Study design

INCLUDE is 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 will complete questionnaires and respond to open-ended questions in a structured interview, and a sub-set will additionally complete a semi-structured interview.

Measures to minimise risk of exposure to COVID-19

INCLUDE is a COVID-19 rapid response study. It is designed to be COVID-safe by avoiding any risk to research participants and research staff. To be fully compliant with Government and University of Exeter COVID-19 guidelines, there will be no face-to-face contact between researchers and research participants, and all research procedures will be conducted over the telephone or online. Any possible risk of research participants being exposed to COVID-19 by handling documents sent in the post will be minimised by providing information and taking consent verbally; written information will only be sent to participants who request to receive it. The study has also been designed to operate

in a way that avoids placing any burden on frontline NHS workers. Research interviews will be conducted over the telephone or online by team members at the IDEAL-2 co-ordinating centre in Exeter and not by NHS Clinical Research Network staff at IDEAL-2 study sites.

Setting

Participants will be interviewed in their normal place of residence by researchers working remotely.

Participant eligibility

Eligible participants will be all those people living with dementia, and their primary informal carers, usually spouses or other close family members, who have previously participated in the IDEAL cohort study and either remained in the study at the most recent assessment point or, if unable to participate at that point, indicated willingness to be contacted again at the next assessment point. People with dementia can take part regardless of whether they have a carer participating, and carers can take part even if the person with dementia whom they support is not taking part.

Only those individuals who have capacity to give informed consent to participation will be included.

The usual IDEAL programme exclusion criteria, which relate to risks to research staff conducting home visits and co-morbid terminal illness of the participant, will not apply to INCLUDE. There are no additional exclusion criteria.

METHOD

Recruitment

Eligible participants will be identified from IDEAL-2 study records, which are held securely in a bespoke study database at Exeter Clinical Trials Unit (ExeCTU), by the IDEAL data manager who is based within ExeCTU. Details will be made available to the INCLUDE programme manager, who will allocate participants to individual researchers.

Eligible IDEAL-2 participants will be approached initially by an INCLUDE researcher using the participant's preferred means of communication (e.g. telephone, email). In general where the person with dementia has a carer involved in IDEAL, the initial contact will be with the carer, enabling the researcher to check that the participant's condition remains at a stage where it is feasible and appropriate to approach the participant. Those who are interested in participating will be provided with further information about INCLUDE. They can take as long as they need to consider their decision. For those who are willing, consent will be taken verbally following established IDEAL programme procedures for which ethical approval is already in place. Researchers will only recruit participants able to give informed consent; capacity will be established using the existing IDEAL HRA-approved procedure for assessment of capacity to consent (235712 Assessment of Capacity to Consent) as outlined in the IDEAL -2 Researcher Handbook T5.

The procedure for taking consent is as follows. Potential participants, both people with dementia and carers, will be contacted by telephone or online (e.g. via Skype or Zoom). They will be asked to identify themselves by providing basic information already held by the researcher such as their full name and address. The researcher will review the study information with them and respond to any questions they may have. When a participant is willing to go ahead, the researcher will read each of the consent statements and the participant's responses will be recorded on an encrypted digital audio recorder. No personally-identifiable data will be recorded; instead the researcher will read out the participant's existing IDEAL ID number before taking consent. The recording will initially be stored on a password-protected University-issued computer. The researcher will electronically sign

and date the consent form and this will be held securely with the digital recording of the consent. The recording and form will be downloaded to a password-protected location on a secure University server.

Participants will not receive payment for taking part in INCLUDE.

Procedures

An INCLUDE researcher will interview each participant by telephone or online (e.g. via Microsoft Teams) through either one meeting or several shorter meetings, depending on the participant's preferences. The researcher will use the approaches and procedures developed in Work Package 1 to ensure that conditions for supporting participation are optimal in the circumstances.

All participants will have a structured interview yielding quantitative and some qualitative data, and a sub-set will also have a semi-structured interview yielding qualitative data. Preparatory work in Work Package 1 will include the development of criteria for deciding which participants will be invited to complete a semi-structured interview.

Structured interviews

The structured interview will be developed during Work Package 1 in consultation with members of the ALWAYs PPI group and with our project partners, Alzheimer's Society and Innovations in Dementia. It is expected to include: brief standardised questionnaires covering key areas such as mental health; specially-tailored questions addressing specific features of the current situation; and open-ended questions to elicit relevant aspects of participants' experiences and views. Questionnaire measures may include both newly-introduced measures and measures previously used in IDEAL. The interviews are expected to last about one hour but may be completed over several shorter sessions, according to participant preferences.

In line with established procedures in IDEAL, questions will be prioritised so that there is a core set of key questions expected to be accessible to all, and the interview can be expanded with further questions for those who are able and willing to engage in more detailed discussion. Interviewers will end each conversation with a participant on a positive note.

Semi-structured interviews

The semi-structured interviews will follow a topic guide adapted during preparatory work in Work Package 1 from an HRA-approved IDEAL programme topic guide developed to explore the immediate impact of the COVID-19 pandemic (235712 Interview Guide v.1 29.04.2020 IDEAL CDI). This adaptation will be developed in consultation with members of the ALWAYs PPI group and with our project partners, Alzheimer's Society and Innovations in Dementia. The interviews are expected to last about 30 minutes, but there will be flexibility to accommodate individual participants' preferences for longer or shorter conversations, and if desired interviews can be completed over two or more short sessions. Interviewers will end each conversation with a participant on a positive note.

Safety considerations

Adverse Events and Serious Adverse Events identified during participant interviews will be reported to the Project Co-ordinator and the Chief Investigator by the relevant INCLUDE researcher using the IDEAL-2 Adverse Event Reporting Form.

There is a possibility that some participants may express a degree of distress during their interviews. Interviewers will be trained to respond appropriately and empathically. Short breaks in the interview will be offered if it is appropriate and helpful to do so, or the interviewer may steer the focus to topics that are less emotionally charged, ensuring that any distress has diminished before the interview ends. If necessary the interview can be discontinued and resumed at a later date. The interviewer may agree a call back time to check on the participant, e.g. 24 or 48 hours later.

It is also possible that it may become clear during an interview that the participant is not receiving essential support. In this case the interviewer will, where possible, seek to provide information about possible additional sources of support and how these might be accessed.

In any situation where an INCLUDE researcher suspects there is substantial ongoing risk to a participant's welfare, such as abuse or neglect , or where abuse or neglect is disclosed directly during an interview, the IDEAL programme protocol for protection of vulnerable adults will be followed; this can be found in the IDEAL-2 Researcher Handbook T5. The researcher will inform the participant of the need to share the information with the Chief Investigator and the participant's General Practitioner (GP), will accurately record the relevant facts and/or the nature of any suspicions, and will contact the Chief Investigator. If the participant is in imminent danger, the police and the relevant local Social Services Department will be informed immediately as well as the GP. The Chief Investigator will be responsible for any further action needed.

Follow up

All participants will be asked whether they would like to receive information about INCLUDE findings, and will be advised that they can still be approached about participating in further rounds of IDEAL-2 data collection.

DATA MANAGEMENT

Data to be generated

INCLUDE is 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 will complete questionnaires and respond to open-ended questions in a structured interview, and a sub-set will additionally complete a semi-structured interview.

Planned recruitment

There are approximately 970 eligible participants: 526 people with dementia and 444 carers seen at IDEAL-2 T4, minus any who had already indicated a wish to withdraw at T5 prior to March 2020.

The aim is to conduct structured interviews with up to 300 people with dementia and approximately 300 carers, and to undertake further semi-structured interviews with up to 100 participants (50 dyads each consisting of a person with dementia and a carer).

Data will be collected by the research team over a 6-month period.

Responsibility for data management

INCLUDE Study protocol

Responsibility for data management will reside with the Chief Investigator, with specific activities delegated to the INCLUDE project co-ordinator and/or members of the research team.

Data capture, storage and transfer

Procedures for recording and storing interview data will follow existing IDEAL procedures for telephone and online interviewing which received HRA approval as an amendment to IDEAL-2 ethical approval for England and Wales (235712 18-WA-01110-AM10). Each recording will be associated with an existing IDEAL ID number and no personally-identifiable data will be sought. Interviews will be recorded on an encrypted digital audio-recorder, stored initially on a password-protected University-issued computer, and transferred to a password-protected location on a secure University server. Interview recordings will be stored separately to the recording of consent.

Where necessary, data will be transferred between researchers and between participating Universities using Virtual Private Networks (VPNs) encrypted to recognised standards.

Management of structured interview data

The structured interview is expected to include standardised questionnaires, bespoke questions with categorical response options, and open-ended questions where responses will be recorded as narrative text. The interview will be programmed in an appropriate University-approved online survey platform by the research team and researchers conducting the interview will use this platform to enter participants' responses, either during the interview or by listening to the audio-recording of the interview once it has been completed, or a mixture of the two. Any personally-identifiable information in the audio-recorded narrative text responses, such as names or locations, will be redacted at the point of data entry. Data will be exported into a corresponding SPSS database for analysis by the research team. This database will be configured so that it is consistent with the structure of the existing IDEAL programme datasets to facilitate eventual merging of data by the research team. The dataset stored in SPSS will be fully described using meaningful long variable names together with entries in the data dictionary. An XML file will be generated automatically from these in order to intrinsically describe the dataset. Additional extrinsic, or contextual, information about the datasets will be stored in either text files or Excel spreadsheets.

Management of semi-structured interview data

The semi-structured interviews will be audio-recorded and professionally transcribed. Appropriate agreements will be put in place with transcribers to protect participant confidentiality. During transcription any personally-identifiable information will be redacted. Transcripts will be managed and analysed using NVivo software. In cases where direct quotations are used in reports of the findings, participants may be assigned pseudonyms, depending on relevant conventions.

DATA ANALYSIS

Analysis of statistical data

Quantitative data will be summarised and reported in a cumulative process as each set of 50 responses is completed. This task will be undertaken by the INCLUDE researchers and data analyst, with guidance from INCLUDE co-investigators and the IDEAL programme statistician, who will form a working group to support the analyses.

We will examine responses for the whole sample and, as sufficient data become available, by sub-group. Sub-groups will be defined by demographic (e.g. age, sex, education) and dementia-related

(e.g. diagnosis, degree of cognitive impairment) characteristics and by indicators of inequality (e.g. socioeconomic status, household income, area-level deprivation).

Once sufficiently extensive, data will be analysed in relation to participants' existing survey data, allowing us to identify the impact of COVID-19 on key indicators, assessed in many cases over 4 previous time-points, such as dementia-related symptoms, mental health, social and psychological well-being, and relationship quality. Trajectories will be investigated using latent class growth curve models, which are robust to missing data and can investigate multiple outcomes and inter-relationships. Factors associated with different types of trajectories will be explored.

We will use Actor-Partner Independence models (APIM) to examine reciprocal influences within dyads. Since this is beyond the scope of traditional statistical methods, the IDEAL team has been developing novel analytic approaches and applying these to the cohort data. These approaches incorporate a third level of data where the carer acts as an informant on behalf of the person with dementia. Building on existing work in IDEAL exploring reciprocal influences of depression (Wu et al., 2019) and perceptions of relationship quality (Rippon et al., 2019), we will employ these methods to explore dyadic data in the current study.

Analysis of narrative text responses to open-ended questions

Responses to open-ended questions in the structured interview will be coded cumulatively in batches using content analysis, starting once the first 25 responses have been logged. This method has already been extensively used in IDEAL to analyse text from open-ended responses. The analysis will be undertaken by INCLUDE researchers, with each researcher acting as both primary and secondary coder to ensure consistency of coding and credibility of the resulting accounts of participants' perspectives.

Researchers will receive training and guidance from a small working group of INCLUDE co-investigators who have previously contributed to such analyses in IDEAL. Analysis of qualitative interview data

Semi-structured interviews will be professionally transcribed. During transcription any personally-identifiable information will be redacted. Analysis will be conducted in NVivo.

Data from the semi-structured interviews will be analysed using framework analysis. This method has been selected because (a) it generates evidence that is securely grounded in the accounts of participants; (b) it is systematic, methodical and comprehensive; (c) it is useful for understanding changes over time; and (d) it is well-suited to characteristics of the current study, such as specific research questions relating to a priori issues, a limited time-frame, and a pre-designed sample (Srivastava & Thomson, 2009).

The interview data will be analysed inductively in an ongoing process starting once the first 5 sets of interviews (each set consisting of an interview with the person with dementia and an interview with that person's carer) are available, with the researcher responsible for conducting the interviews taking a primary role. Analysis will proceed through the six stages of the framework approach (Gale et al., 2013):

- Familiarisation – the researcher will listen to the recordings and read the transcripts to become fully immersed in the data and gain awareness of the key ideas, concepts and themes that relate to the research questions.

- Open coding – the transcripts will be coded line-by-line, with a proportion being independently coded by a second researcher. Codes will be developed initially from the first 10 sets of interviews and further codes can be added as more transcripts are analysed.
- Identifying an analytical framework – the codes covering the ideas, concepts and themes expressed by the participants will be grouped into categories and developed into a framework that can be used to classify and categorise the data. The working group will review the categories and codes, and agree on a set of codes to be applied to subsequent transcripts; this will be updated as additional transcripts are analysed.
- Indexing – all sections of the data relating to each code will be indexed with details of the relevant code.
- Charting – a matrix will be generated in a spreadsheet and data will be summarised by category and code, with illustrative quotations.
- Mapping and interpretation – the information in the chart will be reviewed by the working group and discussed with ALWAYs group members (PPI representatives) to aid interpretation of the findings. Key findings will be summarised in a schematic diagram.

Those INCLUDE co-investigators with expertise in qualitative research will form a working group to support the analysis of qualitative data through regular discussion and review of emerging themes, and cross-coding of data to enhance the credibility and trustworthiness of the findings.

DATA ACCESS

Access to data

During the period in which the INCLUDE study is active, only members of the INCLUDE and IDEAL-2 research teams will have access to INCLUDE data. Access will be subject to the provisions of the IDEAL Programme Data Sharing Policy. Preparation of publications and other outputs based on the data will be subject to the IDEAL Programme Publications Strategy and Policy.

Archiving

Anonymised data from INCLUDE will be made available for data sharing following completion of the study. This will be subject to individual participant consent; if any participants refuse consent for data sharing, their data will be removed from the dataset prior to making it available.

Data from INCLUDE will be deposited with the UK Data Archive within three months of the end date of the study in line with funder requirements, and will be available to prospective users in line with standard operating procedures following the designated embargo period. Responsibility for data archiving will reside with the Chief Investigator, with specific activities delegated to the INCLUDE project co-ordinator and/or members of the research team.

Data from Time-points 1 – 3 of the IDEAL programme have been deposited with the UK Data Archive: quantitative data under Reshare record 854293 http://reshare.ukdataservice.ac.uk/854293/ and qualitative data under Reshare record 854317 http://reshare.ukdataservice.ac.uk/854317. INCLUDE data will be archived in connection with these IDEAL datasets.

WORK PACKAGE 3: DEVELOPING THE LILAC TOOLKIT

Timeline: Months 2 – 18, covering preparation Months 2 – 3; development Months 4 – 12; optimisation and dissemination Months 13 – 18.

Emerging findings will indicate key areas of need. The INCLUDE team will work with the ALWAYs group and with partner organisations Alzheimer's Society and Innovations in Dementia to understand how these needs can be addressed, establish the most suitable formats to reach target groups, including those who do not access the internet, and develop a set of resources to form the Living Well Alongside Coronavirus (LILAC) toolkit.

On an ongoing monthly basis starting from Month 4 we will summarise INCLUDE findings and provide briefings on key issues to our project partners and other interested bodies.

Identifying what resources are needed

An INCLUDE working group will operate flexibly to examine emerging findings, identify the needs to be addressed, consider the types of resources that are most suited to meeting these needs, and identify the relevant target groups to whom the resources should be directed.

While we cannot pre-judge exactly what will be needed, from our experience we anticipate that LILAC resources will be directed at supporting people with dementia and carers and offering guidance to health, social care and voluntary sector staff. For example, given the changes in health professionals' practice with introduction of virtual clinics and telephone consultation, our data will allow us to provide guidance for health professionals about which approaches are most suitable for, and preferred by, people with dementia and carers. As statistical analyses illuminate the impacts on trajectories of symptoms and well-being, we will add evidence-based ways of mitigating negative effects. For example, people with dementia have expressed concerns that physical distancing may lead to more rapid loss of skills; if so, we can develop practical resources to support everyday functioning and skills-maintenance, based on experience in the NIHR-funded GREAT trial.

The working group will draw on expertise from the wider IDEAL network and where appropriate also on expertise available through other collaborations and networks. These may include, but are not limited to, networks of people with lived experience of dementia such as the Dementia Engagement

and Empowerment Project (DEEP) network, groups representing family carers such as Together in Dementia Everyday (TiDE), groups such as the National Dementia Action Alliance, professional networks such as the British Psychological Society Faculty of Psychology of Older People, the British Geriatrics Society, and Dementia UK, government bodies such as Public Health England, and areas of expertise within NHS England/NHS Improvement.

Preparation of resources

The INCLUDE team will work with designers, illustrators, copy-editors, printers, video-makers and web developers to create an accessible and engaging set of resources in a range of formats. We will have a dedicated website ready by Month 2. The first components of the Living Well Alongside Coronavirus (LILAC) toolkit will be ready from Month 6. A comprehensive set of resources will be available by month 12 and further developed and optimised by the end of the project.

Dissemination and impact

We will publicise the LILAC toolkit with support from our partner organizations. We anticipate that LILAC will be primarily hosted by Alzheimer's Society to ensure it is accessible to all who can benefit. Alzheimer's Society Policy Team will co-publish a rapid report outlining INCLUDE findings and introducing the LILAC toolkit. We will aim to engage a wide range of networks including among others the Department of Health and Social Care, NHS England, NHS Improvement, Public Health England, Dementia UK, and the National Dementia Action Alliance.

We will track the use of LILAC to assess its reach and impact. End users will include people living with dementia and their families, health professionals, social care staff and voluntary sector staff. We will compile information on: feedback from end users; citations in guidance, reports, training materials, training courses, and policy documents; number of views and downloads; social media activity; and media coverage.

We expect that LILAC will not only support people affected by dementia and those providing care and services, but also stimulate the growth of new initiatives to enable communities to better manage the impact of endemic COVID-19 on people affected by dementia.

PROJECT MANAGEMENT

Management structures

The INCLUDE Chief Investigator and Co-investigators will together constitute the INCLUDE Project Management Group. The INCLUDE Project Management Group will report to the wider IDEAL Programme Project Management Group. The IDEAL Programme Project Advisory Group, which acts as a 'critical friend' to the programme, will have oversight of INCLUDE. This group already includes representatives of ESRC and Alzheimer's Society as programme funders.

Roles and responsibilities of study management groups and individuals

The INCLUDE Chief Investigator and Co-investigators will together constitute the INCLUDE Project Management Group, which has overall responsibility for the conduct of the study. Responsibility for day-to-day management of the project and research team will be delegated by the Chief Investigator to the INCLUDE Project Co-ordinator. A comprehensive delegation log will be prepared outlining the specific responsibilities of each individual research team member at the outset of the study, and updated as needed.

Role of the ALWAYs group

The ALWAYs (Action on Living Well: Asking You) patient and public involvement group, facilitated by partner organisation Innovations in Dementia through Co-investigator Rachael Litherland, is made up of experts by experience who will contribute to co-production of INCLUDE interview protocols, interpretation of findings, preparation of resources, and dissemination. The ALWAYs group is represented on the IDEAL Programme Project Management Group and Project Advisory Group, and will be represented on the INCLUDE Project Management Group by Rachael Litherland.

QUALITY ASSURANCE

Training

All members of the INCLUDE research team will undertake training in Good Clinical Practice at the start of the study or, if already trained, will update their training as appropriate during the course of the study. They will also receive training in how to operate in a COVID-safe manner according to the latest UK Government and University of Exeter guidance.

New research team members will receive comprehensive induction training and bespoke training specific to their roles. Training will cover the following areas:

- Mandatory University training for research staff, including modules on Information Security and Research Integrity.
- Understanding the INCLUDE protocol and study procedures, and the relevant IDEAL programme policies and procedures such as the IDEAL Programme Publications Strategy and Policy, Data Sharing Policy, Researcher Handbook T5, standard operating procedures and safety reporting procedures. This will be provided by INCLUDE co-investigators.
- Understanding dementia and caregiving, skills in interviewing people with dementia and carers handling digressions and expressions of difficulty or distress during structured and semi-structured interviews, and responding empathically. This will be provided through online masterclasses prepared by the IDEAL team and bespoke training by INCLUDE co-investigators and if possible members of the ALWAYs group.
- Procedures for Protection of Vulnerable Adults including the specific protocol used in the IDEAL programme, details of the statutory support frameworks set out in the Care Act and other relevant legislation, guidance issued by the NHS, NICE and voluntary organisations such as Alzheimer's Society, Dementia UK and Carers UK, and information about helplines and sources of support. This will be provided by INCLUDE co-investigators.
- Understanding the concepts and theories underpinning the IDEAL programme, the findings and evidence accumulated to date, and the resulting theoretical developments. This will be provided through bespoke training by the Chief Investigator.
- Managing and analysing quantitative and/or qualitative data. This will be provided by INCLUDE co-investigators.

All team members will engage in regular peer supervision and team discussion to support researcher well-being and quality of work and address any difficulties or challenges that may arise.

Monitoring, audit and inspection

The Sponsor will hold responsibility for monitoring the research. All study records will be made available to the Sponsor, funder or other appropriate regulatory authority for audit on request.

ETHICAL AND REGULATORY CONSIDERATIONS

Patient and public involvement (PPI)

Patient and public involvement will be integral to the INCLUDE study. The Action on Living Well: Asking You (ALWAYs) PPI group of people with dementia and carers that supports the IDEAL programme (Litherland et al., 2018) will form a key part of the INCLUDE team, providing advice and contributing to co-production of methods and resources.

The ALWAYs group is facilitated and supported by partner organisation Innovations in Dementia, and members are paid for their time at current INVOLVE rates (https://www.invo.org.uk/). The membership includes people from different parts of the country, with different backgrounds and skills and experience of living with different types of dementia. The group has a rolling membership, with individuals able to participate for as long as they wish and feel able to. The ALWAYs group has never operated under a traditional advisory network model involving fixed group meetings, which are often inappropriate for people with dementia or carers because of distance, confidence, or communication or memory problems. ALWAYs operates flexibly and allows individuals to participate in ways that suit them, with a mixture of individual and small group contact conducted online, by telephone and in person. This means that ALWAYs group members can readily adapt to working flexibly in INCLUDE, using online and telephone contact.

Research Ethics Committee (REC) and other regulatory review and reports

For regulatory purposes, INCLUDE will be considered an additional component to the IDEAL programme. IDEAL-2 has current HRA approval through Wales Research Ethics Committee 5 and Scotland A Research Ethics Committee. As we have previously experienced very long delays in receiving responses from the Scotland A Research Ethics Committee, we expect it will be necessary for pragmatic reasons to restrict INCLUDE recruitment to those participants living in England and Wales. The number of participants in Scotland is in any case relatively small.

We will seek approval for INCLUDE as a substantial amendment to the IDEAL-2 approvals for England and Wales. We expect that this submission will be prioritised by HRA as it covers COVID-19 related research. Current IDEAL-2 approvals include permission for face-to-face structured and semi-structured (qualitative) interviews to be conducted directly by research team members in addition to the usual procedure where data are collected by Clinical Research Network (CRN) staff at NHS sites. In England and Wales we have already gained permission for the research team to conduct semi-structured interviews with IDEAL-2 participants using telephone and online methods instead of face-to-face meetings.

The Chief Investigator or designated INCLUDE team member will provide annual reports to the REC within 30 days of the anniversary of the date on which the REC issued a favourable opinion, and will notify the REC of the end of the study or any premature termination of the study.

Within one year of the end of the study, the Chief Investigator or designated INCLUDE team member will submit a final report outlining the results, including any publications and abstracts, to the REC.

The Sponsor will receive progress reports as required and a final report once the study has been completed.

Progress reports will be also provided to the funder in accordance with funder requirements.

Peer review

Plans for the INCLUDE study have been peer-reviewed as part of the application for funding.

Regulatory compliance

Before INCLUDE data collection commences, the Chief Investigator will ensure that appropriate approvals are in place.

If any amendments are required the Chief Investigator, in agreement with the Sponsor, will ensure that information is submitted to the REC in order for that body to issue approval for the amendment. Amendments will only be implemented once approval has been granted.

Protocol compliance

Accidental protocol deviations will be reported to the Project Co-ordinator, Chief Investigator and Sponsor immediately. An Exception Report will be prepared by the Project Co-ordinator, covering a summary and chronology of events, an assessment of risk and details of the corrective actions to be taken. The Chief Investigator will monitor all deviations, ensure that the necessary corrective actions are taken, and identify and address through preventive action any instances where a deviation recurs.

Notification of serious breaches to Good Clinical Practice (GCP) or to the protocol

Serious breaches to Good Clinical Practice or to the protocol will be reported to the Chief Investigator and Sponsor immediately. The Chief Investigator will work with the Sponsor to ensure that appropriate action is taken.

Data protection and participant confidentiality

INCLUDE will adhere to the principles of the General Data Protection Regulation (2018). The Data Protection Impact Assessment carried out for IDEAL-2 will apply to INCLUDE.

Personal data held by the IDEAL programme under approved procedures and with participant consent will be used only to identify and contact potentially eligible participants for INCLUDE. These data will be held securely in line with existing IDEAL programme procedures.

Data collection in INCLUDE will only take place where participants have explicitly provided informed consent. All recorded data will be identified by an existing IDEAL ID number and personal details will not be used to identify participants.

If participants provide personally-identifiable data during audio-recorded INCLUDE interviews, this information will be redacted during data entry or transcription. Therefore, the records used by researchers for purposes of analysis will not contain personally-identifiable data.

Audio-recordings of interviews will be stored securely as outlined in the Data Management Plan. On completion of INCLUDE, the Chief Investigator and Sponsor will identify the appropriate time period for which these records should be retained. At the end of this period the recordings will be erased.

Participant confidentiality will be maintained at all times except where concerns about participant safety override the requirement for confidentiality. INCLUDE researchers will ensure that no individual can be personally identified from anything that is written or said about the research.

Ownership of copyright and intellectual property

The University of Exeter will hold and maintain intellectual property rights and copyrights on all data generated in the INCLUDE study. Any copyright or intellectual property issues arising from the project will be managed by the University of Exeter in accordance with its institutional policy. Agreements will be put in place with collaborating institutions and organizations regarding the rights and contributions of individuals working in those institutions and organizations by the University of Exeter at the start of the research.

Conflicts of interest

The INCLUDE Chief Investigator and Co-investigators have no conflicts of interest to declare. Should a conflict of interest arise in the future, it is the responsibility of the individual concerned to inform the Chief Investigator. In the event that the conflict arising applies to the Chief Investigator, she will inform the Sponsor.

Indemnity

Insurance for Professional Indemnity and Public Liability is provided by the University of Exeter's Insurers via the Insurance Audit & Risk Team, Lafrowda House, St Germans Road, Exeter EX4 6TL.

Protocol amendments

Any amendments to the protocol will be documented in the Amendment History section and the protocol version and date will be revised accordingly.

Access to the final dataset

During the lifetime of the INCLUDE project, only INCLUDE research team members will have access to the dataset, subject to completing the data sharing agreement. On completion of the project, INCLUDE data will be deposited with the UK Data Archive.

DISSEMINATION AND PUBLICATION

Dissemination policy

Policy on dissemination of findings from INCLUDE will follow the provisions of the IDEAL programme Publications Strategy and Policy. Preparation of publications and other outputs based on the data will be subject to the IDEAL Programme Publications Strategy and Policy, which will be amended to incorporate instructions on INCLUDE-specific acknowledgements and information about access to the final dataset.

The INCLUDE team will have regard for the specific requirements regarding dissemination of findings from COVID-19 rapid response projects set out by ESRC and will ensure that research data and findings are shared as widely and rapidly as possible.

Authorship eligibility

Authorship eligibility will be determined in accordance with the provisions of the IDEAL Programme Publications Strategy and Policy.

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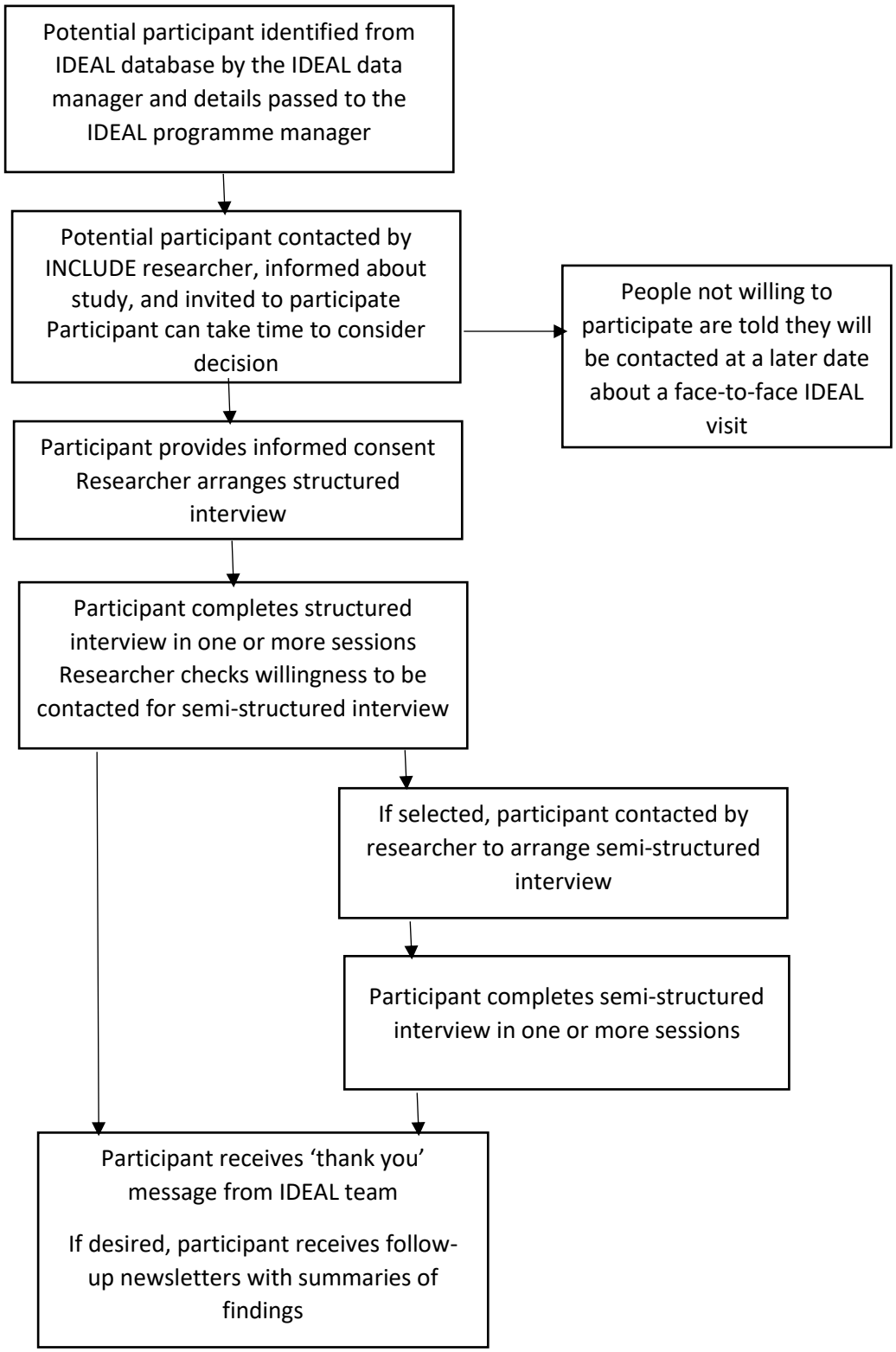
APPENDICES

Appendix 1. INCLUDE study flow chart

Appendix 2. INCLUDE study timelines

Appendix 1. INCLUDE study flow chart



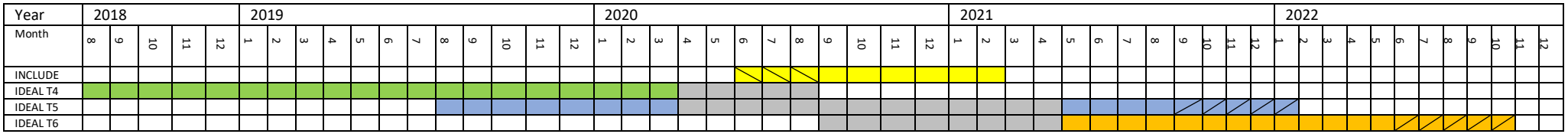
Appendix 2. INCLUDE study timelines

Figure 1. INCLUDE study timelines

Month		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
WP 1	**Develop the data module**																		
	Develop interview protocols																		
	Submit ethics amendment																		
	Develop interview methods																		
	Complete study set-up																		
	Recruit researchers																		
	Train researchers																		
WP 2	**Data collection and analysis**																		
	Recruit participants																		
	Conduct interviews																		
	Analyse data																		
	Write up findings for publication																		
	Prepare data for archiving																		
WP 3	**Develop the LILAC toolkit**																		
	Preparatory work																		
	Prepare briefings on key findings																		
	Identify needs and resources																		
	Develop resources for LILAC																		
	Further develop and optimise LILAC																		
	Disseminate and publicise LILAC																		
	Prepare policy report																		

Figure 2. INCLUDE data collection in relation to the IDEAL programme

INCLUDE data collection will take place during the period of interruption to IDEAL data collection resulting from the COVID-19 pandemic, which is expected to be of 12 months' duration



Key

	INCLUDE preparatory work
	INCLUDE data collection period (may start sooner if preparatory work is completed)
	Expected interruption to IDEAL data collection
	IDEAL-2 Time 4 data collection
	IDEAL-2 Time 5 data collection
	IDEAL-2 Time 5 envisaged extension to data collection period
	IDEAL-2 Time 6 data collection
	IDEAL-2 Time 6 envisaged extension to data collection period