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Achieving Quality and Effectiveness in Dementia Using Crisis Teams (AQUEDUCT): A Randomised Controlled Trial of a Resource Kit for Teams Managing Crisis in Dementia

Short Study Title: AQUEDUCT Main Trial

Sponsor: Nottinghamshire Healthcare NHS Foundation Trust

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Chief Investigator: Professor Martin Orrell, Institute of Mental Health, Nottingham

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This protocol does not have regard to the HRA guidance and order of content.

1 Study Summary

Full Study Title	Achieving Quality and Effectiveness in Dementia Using Crisis Teams: A Randomised Controlled Trial of a Resource Kit for Teams Managing Crisis in Dementia.
Short Study Title	AQUEDUCT Main Trial.
Study Design	The Achieving Quality and Effectiveness in Dementia Using Crisis Teams (AQUEDUCT) programme aims to improve quality and effectiveness of care for people with dementia experiencing a mental health crisis. The programme overall is comprised of three separate work packages (WPs). This Work Package 3 (WP3) will evaluate *via* a randomised controlled trial (RCT) an intervention consisting of an online Resource Kit (RK) (developed in Work Packages 1 and 2) for use by Teams Managing Crisis in Dementia (TMCDs), to inform impact on hospital admissions and costs, and the experience of people with dementia and carers receiving input as well as TMCD practitioners using the Resource Kit. This study will consist of 2 research sections: 3.1: A randomised controlled trial of an online Resource Kit for use by Teams Managing Crisis in Dementia. 3.2: A qualitative evaluation of the experience of using, or receiving input from a TMCD using, the Resource Kit.
Study Participants	This study will include practitioners working in TMCDs, people with dementia in receipt of input from TMCDs, and carers.

Study Sample Size	**WP3.1: Randomised Controlled Trial of the Resource Kit** TMCD practitioners (total approx. 144) and people with dementia or carers (total approx. 240) from 24 TMCDs will be recruited. *Overall total 384*. **WP3.2: Qualitative Evaluation of the Experience of Using, or Receiving Input from a TMCD Using, the Resource Kit** 36 study-specific questionnaires will be completed by purposively sampled TMCD practitioners (3 *per* TMCD) from the intervention arm only. A total of 12 semi-structured interviews (conducted remotely) will be completed with purposively sampled people with dementia or carers from across TMCDs participating in the intervention arm only. *Overall total 48*. *Overall participant contacts: 432 participants (TMCD practitioners: 180; people with dementia and carers of people with dementia: 252).*
Study Locations	24 TMCDs across England, and the Institute of Mental Health (IMH), Nottingham
Participant Inclusion Criteria	**WP3.1: Randomised Controlled Trial of the Resource Kit** • Teams managing mental health crises in dementia in community settings, and practitioners, people with dementia and carers associated with these TMCDs. **WP3.2: Qualitative Evaluation of the Experience of Using, or Receiving Input from a TMCD Using, the Resource Kit** • Practitioners completing a questionnaire will be purposively selected from TMCDs which have participated in the intervention arm of the RCT. • People with dementia participating in a remote, semi-structured interview will (1) have a diagnosis of dementia, (2) have received input within the previous 6 weeks from a TMCD which has participated in the intervention arm of the RCT, and (3) be able to report on the input they received. • Carers participating in a remote, semi-structured interview will have provided support for a person with dementia who

	has received input within the previous 6 weeks from a TMCD which has participated in the intervention arm of the RCT.
Team Exclusion Criteria	TMCDs will be excluded for the following reasons: • Team is not defined by service/NHS Trust as having a role in dementia mental health crisis management. • Team does not meet the following definition for mental health crisis: *providing urgent mental health assessment and intervention for people with dementia in the community*. • A major service reorganisation is planned over the study period, or is anticipated in the near future. • NHS Trust and team are not able to demonstrate capacity and capability to complete required research activities. • Team is co-located with another team taking part in this study; sharing the same site is acceptable but sharing the same office is not. • Team shares immediate management structures with another team taking part in this study; sharing a management structure above the level of team leader is acceptable but sharing a team leader is not. • Core clinical staff for team do not operate separately from another team taking part in this study; this includes a requirement that core clinical staff must not engage in clinical cross cover with another team taking part in this study. • Team shares core administrative staff with another team taking part in this study. • If a team leader who has been exposed to the intervention becomes lead for a team in the control arm of the RCT, that latter team will then be excluded.
Main Aims of the AQUEDUCT Research Programme	The AQUEDUCT research programme aims to improve quality and effectiveness of care for people with dementia experiencing a mental health crisis, and to investigate consequential impact on hospital admissions and costs, and experiences for people with dementia and carers receiving input.

Study (WP3) Aims	The aims for this study (WP3) are: 1. To conduct a randomised controlled trial of the Resource Kit to evaluate impact on hospital admissions and costs. 2. To gather feedback from participants in the intervention arm of the RCT (people with dementia and carers receiving input as well as TMCD practitioners using the Resource Kit) about their experience of the intervention.
Intervention	The Resource Kit (RK).

2 Abbreviations

AE	Adverse Event
AQUEDUCT	Achieving Quality and Effectiveness in Dementia Using Crisis Teams
BPSD	Behavioural and Psychological Symptoms of Dementia
BPT	Best Practice Tool
CEBM	(Oxford) Centre for Evidence-Based Medicine
CI	Chief Investigator (Professor Martin Orrell)
CMHT	Community Mental Health Team
COVID-19	(Novel) Coronavirus Disease 2019 (WHO nomenclature)
CRF	Case Report Form
CRHTT	Crisis Resolution and Home Treatment Team
CRN	Clinical Research Network
CRT	Crisis Resolution Team
CSQ-8	Client Satisfaction Questionnaire – 8 item version
DMC	Data Monitoring Committee
EM-CRN	East Midlands Clinical Research Network
EQ-5D-5L	EuroQoL quality of life questionnaire – 5 + 5 item version
FM	Fidelity Measure
GCP	Good Clinical Practice
GDPR	General Data Protection Regulation
GHQ-12	General Health Questionnaire – 12 item version
HRA	Health Research Authority
HTP	Home Treatment Package
HTT	Home Treatment Team
IMH	Institute of Mental Health, Nottingham
IQR	Interquartile Range
ITT	Intention to Treat

MAR	Missing At Random
MCID	Minimum Clinically Important Difference
MLM	Multilevel Modelling
MRC	Medical Research Council
NHS	National Health Service
NIHR	National Institute for Health Research
NottsHC	Nottinghamshire Healthcare NHS Foundation Trust
PMG	Programme Management Group
PPI	Patient and Public Involvement
PSG	Programme Steering Group
PSS	Personal Social Services
QALY	Quality-Adjusted Life Year
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
RK	Resource Kit
R&E	Research and Evidence Department
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SD	Standard Deviation
SHIELD	Support at Home – Interventions to Enhance Life in Dementia
TAU	Treatment As Usual
TMCD	Team Managing Crisis in Dementia
TMG	Trial Management Group
TSG	Trial Steering Group
UoN	University of Nottingham
UWES	Utrecht Work Engagement Scale
WAAQ	Work Acceptance and Action Questionnaire
WP	Work Package

3 Study Personnel and Roles

Trial Management Group (TMG) members:

Professor Martin Orrell	Chief Investigator
Professor David Challis	Co-investigator
Professor Tom Dening	Co-investigator
Dr Juanita Hoe	Co-investigator
Dr Bryn Lloyd-Evans	Co-investigator
Professor Esme Moniz-Cook	Co-investigator
Professor Steve Morris	Co-investigator, Health Economics lead
Professor Fiona Poland	Co-investigator, PPI lead
Mr David Prothero	Co-investigator, PPI member
Dr Boliang Guo	Statistician
Dr Donna Maria Coleston	Programme Manager, Trial Manager

Conflicts of interest

No conflicts of interest have been reported.

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4 Programme Rationale

4.1 Dementia background

It is estimated that there are 850,000 older people in the UK living with dementia [1], with a major impact on services costing over £17 billion a year, even taking into account family caregivers who are estimated to save over £6 billion of further costs a year. Over coming decades, as the ageing population increases, it is anticipated that there will be an increasing number of people with dementia living at home.

The Prime Minister's Challenge on Dementia [2] identified improving dementia care as a key priority likely to have an enduring impact, but there remains a need to respond to this major policy initiative. The National Health Service (NHS) Institute for Innovation and Improvement [3] estimated that using psychological interventions instead of antipsychotic drugs for behavioural and psychological symptoms of dementia (BPSD) could save £54 million a year by reducing risk of stroke, falls and other related NHS costs. In addition, home-oriented care is a key objective of the National Dementia Strategy [4], but fluctuations in the health and social circumstances of the person with dementia require skilled management to prevent a breakdown in their care that may lead to crisis. This can include and go beyond BPSD that frequently create circumstances that render care at home unviable; however, if steps can be taken to manage these issues, then this could reduce overall costs.

4.2 Crisis and use of Teams Managing Crisis in Dementia (TMCDs)

An Alzheimer's Society report found that one in ten respondents reported a relative with dementia admitted into hospital unnecessarily due to lack of access to community support [1]. For the working age population without dementia, there are specific services to avoid such hospital admission, namely Crisis Resolution Teams (CRTs), which appear to be well integrated and mainstream; however, people with dementia in crisis and their carers are often managed through a variety of channels including Community Mental Health Teams (CMHTs), Crisis Resolution and Home Treatment Teams (CRHTTs), generic older people's rapid response teams, and in some instances, there are no suitable services available at all. Crisis situations are complex, but in the working age population crisis teams seem to be effective in reducing admission rates [5-9] and result in higher levels of satisfaction amongst patients [5,6] and family caregivers [9]. There are many evaluations of services available to the working age population [5-7, 10-11], but less is known about the effectiveness of services for older people, especially in relation to dementia. When people with dementia, caregivers, and practitioners are asked about the experience of crisis and its management, both carers and practitioners value a more coordinated and proven approach [12].

There has been an increase in recent years in the development of teams to support people with dementia at home, and these are now a key component of many mental health services for older people. The key aim of these services is to reduce or if possible avoid hospital admissions, increase

support within the home, and reduce the overall cost of care. The benefits of avoiding hospital admission can include reduced confusion for the person with dementia, reduced concerns of over-medication, and improved quality of care. In addition, learning how to manage crises at home could increase the skills of practitioners, family caregivers and people with dementia, to enable better coping with future crises and delay or perhaps even avoid future institutionalisation. For people with dementia wanting to remain in their own home, and their caregivers, this can improve their healthcare experience by keeping them at home where possible.

A systematic review of crisis interventions for dementia and other mental health problems in older people, which included a scoping exercise to evaluate current models of practice [13], identified three types of crisis team: specialist older people's CRHTTs, generic all-age Home Treatment Teams (HTTs), and intermediate care services. The CRHTTs appeared to be effectively managing crises and reducing admissions, but models were loosely specified with no accepted good standard of care or well defined model of best practice. The review found Grade C (low quality) evidence, using the Oxford Centre for Evidence-Based Medicine (CEBM) guidelines, that CRHTTs are effective in reducing numbers of admissions to hospital. This suggested that crisis intervention approaches could potentially reduce admissions, but the review concluded that there was a lack of evidence supporting the efficacy of CRHTTs and a controlled trial was recommended. Additionally, risk factors for admission to general hospital beds were concerned with physical causes (such as infections), although these could be better managed to reduce bed use.

Home Treatment Packages (HTPs) can be used to help teams manage crises for people with dementia and their family carers, as specialist older people's crisis services have been identified as vital in delivering specialist expertise for this complex issue [14]. Previously, a Home Treatment Package was developed through work conducted as part of the 'Support at Home – Interventions to Enhance Life in Dementia' (SHIELD) programme, a 5 year National Institute for Health Research (NIHR) funded project (RP-PG-0606-1083). Focus groups were run with people with dementia, family caregivers and practitioners to investigate the potential causes of crisis [12]. Results indicated that people with dementia preferred support from family and friends, access to mobile phones, and home adaptations to reduce risk. Practical interventions such as home adaptations, assistive technology, education and training for family carers, and flexible home care services were highly valued during times of crisis by people with dementia and their families who thought they may help to prevent hospital admissions. Both carers and practitioners valued carer training and education, care plans and well-coordinated care, while practitioners also emphasised more intensive interventions such as emergency home respite and extended hours services. These results from the SHIELD study informed development of the AQUEDUCT research programme.

4.3 The AQUEDUCT research programme

To date, because of inadequate study designs, there has been limited evidence to indicate that crisis teams working with older people with mental health needs reduce hospital admissions [8, 9]; so the AQUEDUCT research programme has worked with people with dementia, carers and practitioners to develop a model of best practice for Teams Managing Crisis in Dementia (TMCDs). This model is now the basis of a Resource Kit (RK) for achieving high quality care, which also includes guidance on how TMCDs can achieve best practice. Without the AQUEDUCT programme, there is a risk that crisis teams working with people with dementia may become a disparate collection of teams with poorly defined models, unable to cope with the complex needs of this client group, leading to a wide variation in quality and effectiveness of care provided across the UK.

The National Institute for Health Research (NIHR) Programme for Applied Research is funding the Achieving Quality and Effectiveness in Dementia Using Crisis Teams (AQUEDUCT) research programme, grant number RP-PG-0612-20004. The programme commenced in September 2014, and in September 2018, a time extension was granted by NIHR. The AQUEDUCT research programme will evaluate use of the structured RK in TMCDs across England. As indicated previously, this programme is based on work conducted as part of the 'Support at Home – Interventions to Enhance Life in Dementia' (SHIELD) programme, (NIHR grant number RP-PG-0606-1083).

The AQUEDUCT research team includes leading clinical research experts in dementia care (covering psychiatry, clinical psychology, nursing, social work, occupational therapy, health economics and research methodology) who have significant experience in leading major studies. This programme of research could influence how services are organised, leading to major benefits for people with dementia and carers, by avoiding hospital admissions, improving the quality of service delivery, and reducing care costs.

4.4 Work Packages 1 and 2 (WP1 and WP2)

In the early stages of the AQUEDUCT research programme (WP1), a scoping review reporting on the effectiveness of crisis interventions for older people with dementia together with a survey of dementia crisis teams (to map services, understand operational procedures, and identify current practice) [15] revealed limited evidence in support of crisis teams reducing the rate of hospital admissions, and despite an increase in the number of published studies, methodological limitations remain. The pathway for care managing crisis for people with dementia was noted to vary widely across services in England, and only half of the teams surveyed (51.8%) had a care pathway in place to manage crises. It was concluded that, to provide better evidence on crisis intervention teams, a comprehensive research process is required to deliver a standardised care pathway and measurable intervention as part of a large scale evaluation of effectiveness.

This initial work led on to qualitative research to establish current practice and elements of best practice in TMCDs. From this qualitative work, and through a comprehensive consensus process, a model of best practice was formulated, consisting of 50 Best Practice Statements and an accompanying Fidelity Measure (also known as a 'Best Practice Tool' or BPT) which can be used by TMCDs to determine the extent to which their team conforms to the 'Best Practice Model.' From the Fidelity Measure (FM), a Resource Kit (RK) was constructed to assist teams in improving their practice according to the 'Best Practice Model.' This Resource Kit consists of the Fidelity Measure which enables TMCDs to evaluate their practice, together with a set of relevant templates and documents which TMCDs can amend according to their own needs.

In WP2, a Feasibility Study was conducted to establish the methodology (and its acceptability to people with dementia, carers, and practitioners working in TMCDs) to be used in the randomised controlled trial of this Resource Kit, and a qualitative research element furthered final refining of the Resource Kit. The Feasibility Study revealed the RK to be acceptable to and usable by TMCDs; team practitioners consistently reported that the RK and BPT accurately reflected their clinical practice. Additionally, the Feasibility Study revealed the burden to people with dementia and carers of participating directly in research concerning their TMCD while they themselves were experiencing crisis. Following iterative consultation with both an AQUEDUCT PPI (Patient and Public Involvement) Reference Group and an AQUEDUCT Clinical Staff Reference Group, this next stage of the AQUEDUCT research programme, the RCT in Work Package 3 (WP3), was developed taking into account all lessons learned during the Feasibility Study, and being mindful of additional pressures on the NHS due to the current COVID-19 pandemic.

5 Study Aims and Objectives

5.1 Main Aims of the AQUEDUCT Research Programme

The AQUEDUCT research programme aims to improve quality and effectiveness of care for people with dementia experiencing a mental health crisis, and to investigate consequential impact on hospital admissions and costs, and experiences for people with dementia and carers receiving input.

5.2 Study (WP3) Aims

1. To conduct a randomised controlled trial of the Resource Kit (RK) to evaluate impact on hospital admissions and costs.
2. To gather feedback from participants in the intervention arm of the RCT (people with dementia and carers receiving input as well as TMCD practitioners using the Resource Kit) about their experience of the intervention.

5.3 Specific Objectives

This study will address the following objectives; it will:

1. Evaluate impact of use of the Resource Kit (RK) by TMCDs on psychiatric hospital admissions for people with dementia in the geographical catchment area covered by the TMCD.
2. Evaluate impact of use of the Resource Kit (RK) by TMCDs on acute/general hospital admissions for people with dementia in the geographical catchment area covered by the TMCD.
3. Evaluate impact of use of the Resource Kit on those receiving input from the TMCD using the RK, (people with dementia and carers of people with dementia).
4. Evaluate impact of use of the Resource Kit on TMCD practitioners using the RK.
5. Explore the possible mechanism of action of the RK *via* comparison of Best Practice Tool (BPT) scores for TMCDs in the intervention arm across the duration of the study period.
6. Evaluate costs associated with use of the Resource Kit by TMCDs.
7. Explore the experience of participants regarding the RK in the intervention arm, (people with dementia and carers receiving input, practitioners using the RK).

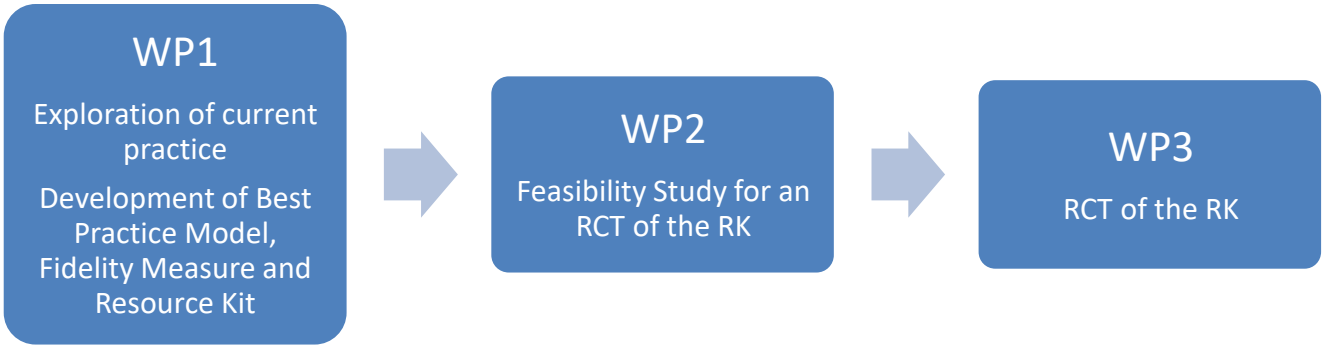
The following table summarises how these objectives will be met, with details of measures to be used, when these measures will be completed, and by whom they will be completed:

Study Objectives	Study Outcomes	Measures to be Used	Relevant To	When Completed
1. To evaluate impact of use of the Resource Kit (RK) by TMCDs on psychiatric hospital admissions for people with dementia in the geographical catchment area covered by the TMCD	Primary outcome measure	• Hospital admissions data for people with dementia to mental health beds, in the geographical catchment area of the TMCD as defined by postcode	TMCDs	Data provided by NHS Trust for TMCD at baseline and 6 months
2. To evaluate impact of use of the Resource Kit (RK) by TMCDs on acute/general hospital admissions for people with dementia in the geographical catchment area covered by the TMCD	Secondary outcome measure	• Hospital admissions data for people with dementia to acute/general hospital beds, in the geographical catchment area of the TMCD as defined by postcode	TMCDs	Data collected from local acute NHS Trust(s) at baseline and 6 months
3. To evaluate impact of use of the Resource Kit on those receiving input from the TMCD using the RK, (people with dementia and carers of people with dementia)	Secondary outcome measures	• Client Satisfaction Questionnaire (CSQ-8) • Quality of Life Questionnaire (EQ-5D-5L) • General Health Questionnaire (GHQ-12)	People with dementia and carers	All measures completed by people with dementia and carers once post discharge from TMCD
4. To evaluate impact of use of the Resource Kit on TMCD practitioners using the RK	Secondary outcome measures	• Work Acceptance & Action Questionnaire (WAAQ) • Work Engagement Scale (Utrecht – UWES) • General Health Questionnaire (GHQ-12) • Staff sickness records	TMCD practitioners	Measures completed by TMCD practitioners, and sickness absence reported by TMCD, at baseline and 6 months
5. To explore the possible mechanism of action of the RK *via* comparison of Best Practice Tool (BPT) scores for TMCDs in the intervention arm across the duration of the study period	Quantitative exploration of data, to describe processes which may underlie possible changes in primary outcome and secondary outcome measures	• Best Practice Tool (BPT) scores collected *via* the Resource Kit	TMCDs	BPT completed by TMCD at baseline and 6 months
6. To evaluate costs associated with use of the Resource Kit by TMCDs	Cost-consequences, cost-effectiveness and cost-utility analyses of the Resource Kit	• Hospital admissions data, listed above • EQ-5D-5L questionnaire, listed above Additionally: • For intervention arm only, activity records completed by TMCD, to monitor time spent implementing the Resource Kit in practice • For intervention arm only, support elements *e.g.* weekly contact (*via* multimedia, telephone call or email) monitored by AQUEDUCT research team, to identify usage and costs • For both study arms, records of i) number of permanent care home admissions, ii) number of respite care admissions kept throughout	People with dementia, carers, TMCD practitioners, (AQUEDUCT research team)	Activity records, support records and care home admissions completed throughout; hospital admissions data and EQ-5D-5L, as above
7. To explore the experience of participants regarding the RK in the intervention arm, (people with dementia and carers receiving input, practitioners using the RK)	Qualitative data collection to describe personal impact of the RK for people with dementia, carers and TMCD practitioners	• Study-specific questionnaire for TMCD practitioners • Semi-structured interview (to be conducted remotely) for people with dementia and carers	People with dementia, carers and TMCD practitioners	Completed following RCT

6 Study Design

6.1 AQUEDUCT Research Programme Outline

The AQUEDUCT research programme uses the Medical Research Council's (MRC) *Framework for the Development and Evaluation of RCTs for Complex Interventions to Improve Health* [16] which describes four phases: (i) development, (ii) feasibility/piloting, (iii) evaluation, and (iv) implementation/long-term dissemination. There are three work packages (WPs) in the AQUEDUCT programme:



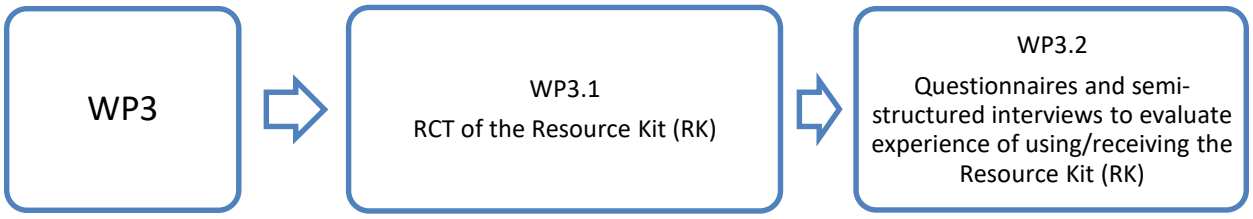
THIS CURRENT PROTOCOL RELATES TO WP3 ONLY.

6.2 WP3: RCT of the Resource Kit

This study (WP3) will evaluate the Resource Kit developed in earlier stages (WP1 and WP2) of the AQUEDUCT research programme. A randomised controlled trial will compare the impact of use of the Resource Kit by teams participating in the intervention arm of the trial with Treatment as Usual (TAU) by teams participating in the control arm of the trial. Specifically, the RCT will examine the impact of use of the RK on hospital admissions relevant for the TMCD and related costs.

A subsequent section of this Work Package will also collect qualitative data *via* questionnaires and semi-structured interviews (the latter to be conducted remotely), to describe participants' experience (people with dementia, carers, and practitioners working in TMCDs) of receiving input from the TMCD using, or (in the case of TMCD staff) of using, the Resource Kit.

The following activities will take place during the two research sections of WP3:



WP3.1: Randomised Controlled Trial of the Resource Kit

Aim

To evaluate the Resource Kit in practice by conducting a randomised controlled trial with a representative sample of TMCDs across England. Specifically, the RCT will evaluate the impact of the RK on hospital admissions and costs, as well as impact on participants.

Design

This pre-post group-comparison RCT will be carried out with 24 TMCDs. TMCD practitioners in the intervention arm (12 TMCDs) will receive training in use of the Resource Kit and will then use it with all instances of dementia crisis screened into their service during their implementation of the RK. TMCD practitioners in the control arm (12 TMCDs) will not have access to the Resource Kit and will conduct TAU. Psychiatric hospital admissions data (Study Objective 1, in the above table) will be required from all participating NHS Trusts on a backdated basis for the 6 month period prior to a TMCD's initiation into the trial; ability to provide these data for admissions to mental health beds relevant for the TMCD catchment area will be a criterion for inclusion in the trial. Acute/general hospital admissions data (Study Objective 2, in the above table) will be collected by the AQUEDUCT research team from local acute NHS Trust(s) relevant to the geographical catchment area of the TMCD on a backdated basis for the 6 month period prior to a TMCD's initiation into the trial; ability to provide precise details of these acute NHS Trust(s) will be a criterion for inclusion in the trial. All hospital admissions data relevant for the TMCD catchment area will also be required/collected at 6 months. Participant-completed measures will be collected from people with dementia (where possible) and carers once post discharge from the TMCD for TMCDs participating in both arms of the study to allow group-wise comparisons (Study Objective 3, in the above table), and participant-completed measures will be collected at baseline and 6 months from TMCD practitioners participating in both arms of the study to allow group-wise comparisons (Study Objective 4, in the above table). The Best Practice

Tool will be completed by TMCDs participating in the intervention arm of the RCT only at baseline and at 6 months (Study Objective 5, in the above table).

This RCT will incorporate an internal pilot, to include the first 4 participating TMCDs, in particular, the first 2 TMCDs entering the intervention arm and the first 2 TMCDs entering the control arm. No formal STOP-GO criteria will be set as this internal pilot will be an opportunity for the AQUEDUCT research team to learn best ways to support TMCD practitioners to engage with people with dementia and carers for the purposes of their recruitment into the study and completion of person with dementia and carer-specific measures. In earlier stages of the AQUEDUCT research programme (Work Package 1 and Work Package 2), recruitment of TMCDs as a whole and of individual TMCD practitioners was consistently to target; therefore, it is anticipated that there will not be difficulties with TMCD or practitioner recruitment in this Work Package 3 (RCT).

Recruitment of TMCDs

24 TMCDs will be purposively recruited from across England to ensure a diverse range of TMCD models and service user demographics. All NHS Trusts seeking to participate in this RCT must confirm that they are able to establish and report to the AQUEDUCT research team all psychiatric hospital admissions, to mental health beds, for people with dementia in the geographical catchment area covered by the TMCD, as defined by postcode. All NHS Trusts seeking to participate must confirm that they can provide precise details of local acute NHS Trust(s) which may admit people with dementia from the geographical catchment area covered by the TMCD, as defined by postcode. All NHS Trusts seeking to participate in this research must confirm that elements from the Resource Kit can be used by TMCDs within their remit during the course of implementation of the intervention; all Trusts will be required to do this in advance of commencement of the trial, regardless of trial arm (intervention or control) to which a particular TMCD is subsequently allocated. All NHS Trusts seeking to participate in this RCT must establish and confirm that TMCDs to be included will identify at the start of the study 3 people with dementia or carers who have accessed the TMCD within the past 6 months, to contribute to completion of the Best Practice Tool; all Trusts will be required to do this in advance of commencement of the trial, regardless of trial arm (intervention or control) to which a particular TMCD is subsequently allocated.

Once the NHS Trust has agreed formally to participate in this research, each TMCD manager or appropriate senior practitioner will receive an information pack which will include an information sheet for potential practitioner participants (Appendix 1). The TMCD manager or appropriate senior practitioner will identify 2 practitioners who can act as volunteer ‘research coordinators’ for their TMCD, and these practitioners will be given up to 3 days from receiving the study information to decide if they wish to participate. A site set-up visit from the AQUEDUCT research team will then take place, during which occasion copies of the information sheet (Appendix 1) and consent form

(Appendix 2) will be reviewed, opportunity for questions given, and consent taken from those TMCD practitioners who wish to act as research coordinators as they themselves will be subject to data collection. From this point on, it will be the responsibility of the TMCD research coordinators to arrange and confirm consent with their fellow TMCD practitioners, following the procedure (to include the time allowance of 3 days for consideration) used for confirmation of their own consent. This delegation of responsibility will be recorded formally in the Site Delegation Log (Appendix 3).

Recruitment of People with Dementia and Carers

People with dementia (where possible, mental capacity allowing) and carers will be recruited on an ongoing basis as they are referred onto the TMCD caseload. People with dementia and carers will be approached by a TMCD practitioner who will give them the appropriate information sheet (Appendix 4 or 5) and explain to them that their particular TMCD has agreed to participate in the AQUEDUCT research programme; so they are being invited to participate in the research also. They will be given up to 3 days to decide if they wish to participate. On first contact with the person with dementia, and at every subsequent meeting with the person with dementia, the TMCD practitioner will determine the mental capacity (according to the Mental Capacity Act 2005) of the person with dementia to give informed consent to take part in the research. Opportunity will be given to ask questions and consent will then be taken (Appendix 6) from the person with dementia. A consent form will be completed separately with the carer regarding their own involvement in the RCT (Appendix 6).

The Intervention – Resource Kit (RK)

The Resource Kit is an online (and therefore, COVID-19 appropriate) resource for TMCDs, designed to assist teams in evaluating and improving their practice according to the 'Best Practice Model' developed in the first work packages of the AQUEDUCT research programme. The RK consists of two components. The first component is a Fidelity Measure (FM) which enables TMCDs to evaluate their practice according to 50 Best Practice Statements and to establish the strengths and weaknesses of their practice. This FM is also known as the 'Best Practice Tool' (BPT). The second component is a collection of documents and paperwork templates which can be used directly or adapted by teams to suit their particular practice. This second component of the Resource Kit is also known as the 'Best Practice Toolkit.' The RK is available as a password-protected online resource. For the purposes of this trial, each TMCD in the intervention arm only will be asked to complete the FM before the intervention phase, to determine areas in which the TMCD could improve practice. The TMCD will then implement relevant elements of the Best Practice Toolkit that will assist in improving practice during the implementation phase, and the team will complete the FM again at the end of the intervention phase (at 6 months). TMCDs in the control arm will not have access to the Resource Kit, will not complete the Best Practice Tool, and will not use elements of the Best Practice Toolkit during the implementation phase of the trial; these TMCDs will continue to conduct treatment as usual (TAU).

Procedures

Details of the AQUEDUCT RCT procedures are presented in Figure 1, below:

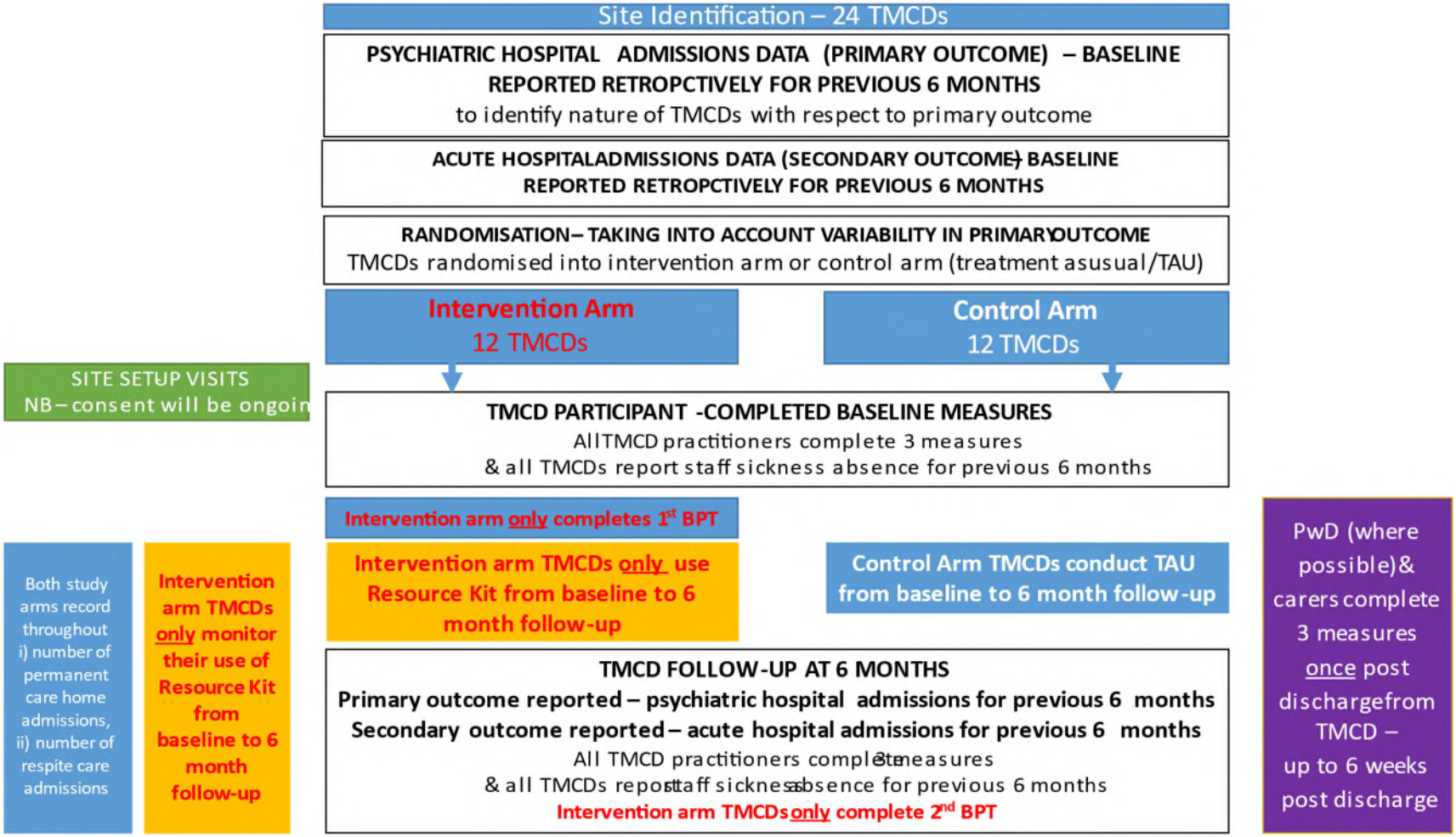


Figure 1 – flowchart of the AQUEDUCT Resource Kit RCT procedure

Procedure for TMCDs:

- 24 TMCDs will be purposively recruited from across England to ensure a diverse range of TMCD models and service user demographics.
- Initial screening of all NHS Trusts and TMCDs will be carried out at the start of the trial by the AQUEDUCT research team, to include details of COVID-19 restrictions in the local area.
- All NHS Trusts seeking to participate in this RCT must confirm that they are able to establish and report to the AQUEDUCT research team all psychiatric hospital admissions, to mental health beds, for people with dementia in the geographical catchment area covered by the TMCD, as defined by postcode.
- All NHS Trusts seeking to participate must confirm that they can provide precise details of local acute NHS Trust(s) which may admit people with dementia from the geographical catchment area covered by the TMCD, as defined by postcode.
- At the start of the trial, all NHS Trust R&E Departments covering the 24 TMCDs wishing to participate will be required to identify and report psychiatric hospital admissions to mental health beds for the preceding 6 month period; this will identify the nature of TMCDs with respect to the primary outcome measure, allowing balanced allocation of TMCDs to the intervention arm and the control arm on this basis.
- At the start of the trial, all NHS Trust R&E Departments covering the 24 TMCDs wishing to participate will be required to provide precise details of local acute NHS Trust(s) which may admit people with dementia from the geographical catchment area covered by the TMCD, as defined by postcode. The AQUEDUCT research team will then be responsible for collecting acute/general hospital admissions data for the preceding 6 month period for the relevant TMCD catchment area.
- When these data have been provided/collected and the NHS Trust has agreed formally to participate in this research, each TMCD manager or appropriate senior practitioner will identify 2 practitioners who can act as volunteer ‘research coordinators’ for their TMCD.
- A site set-up visit from the AQUEDUCT research team will then take place, during which time consent will be obtained from the TMCD practitioners who wish to act as research coordinators as they themselves will be subject to data collection. From this point on, it will be the responsibility of the TMCD research coordinators to arrange and confirm consent with their fellow TMCD practitioners. This delegation of responsibility will be formally recorded in the Site Delegation Log (Appendix 3).
- Practitioners in all TMCDS, those in the intervention arm and those in the control arm, will individually complete 3 questionnaires (WAAQ, UWES, GHQ-12) at baseline.

- Either at the site set-up visit or subsequently, TMCD practitioners in the intervention arm only (12 TMCDs) will review a Research Involvement Guide and will complete digital (and therefore, COVID-19 appropriate) training about completion of the Fidelity Measure (FM) and use of the Resource Kit; these practitioners will then complete a Post-training Self-administered Assessment on the RK, to inform the AQUEDUCT research team of their level of understanding following the RK training.
- Either at the site set-up visit or subsequently, TMCD practitioners in the control arm (12 TMCDs) will review an abbreviated Research Involvement Guide and digital (and therefore, COVID-19 appropriate) training, covering their involvement in research activities (such as completion of measures) only.
- Following the site set-up visit, TMCDs in the intervention arm only (12 teams) will self-complete the FM to identify 'gaps' in their practice; the team will have a maximum period of 2 weeks in which to do this. The TMCD will then have access to the online 'Best Practice Toolkit' which includes work templates and documents that will be useful in addressing these gaps.
- Weekly contact (*via* multimedia means, telephone call or email) will be offered to the TMCD manager or appropriate senior practitioner, to obtain feedback and to provide support for implementation of the RK. In addition, any TMCD practitioner will be able to access email support from the AQUEDUCT research team. These support elements will be monitored, to identify usage and costs.
- For TMCD practitioners in the intervention arm only, activity records regarding the RK will be kept throughout, to monitor time spent implementing the RK in practice during this research.
- For TMCD practitioners in both study arms, records of i) the number of permanent care home admissions and ii) the number of respite care admissions will be kept throughout; these data will be for 'salient admissions' only *i.e*. for those people with whom the TMCD has engaged.
- TMCDs in the intervention arm only will complete the FM again at the end of the intervention phase, at 6 months. On this occasion, teams will again be asked to do this as quickly as possible, taking no longer than 2 weeks.
- The primary outcome measure concerning psychiatric hospital admissions will be re-collected at the 6 month follow-up point for all TMCDs. NHS Trusts for all TMCDs, those in the intervention arm and those in the control arm, will be required to provide again data on all psychiatric hospital admissions, to mental health beds, for people with dementia in the geographical catchment area covered by the TMCD, as defined by postcode, for the preceding 6 month period (*i.e*. the study duration).
- The secondary outcome measure concerning acute/general hospital admissions will also be re-collected at the 6 month follow-up point. NHS Trusts for all TMCDs, those in the intervention

arm and those in the control arm, will be required to confirm/update precise details of local acute NHS Trust(s) which may admit people with dementia from the geographical catchment area covered by the TMCD, as defined by postcode. The AQUEDUCT research team will then be responsible for collecting acute/general hospital admissions data for the 6 month study period for the relevant TMCD catchment area.

- Secondary outcome measures (WAAQ, UWES, GHQ-12) will be re-completed by TMCD practitioners at the 6 month follow-up point; practitioners in all TMCDs will do this, those in the intervention arm and those in the control arm.
- All TMCDs will be required to return all paperwork on an ongoing basis to the AQUEDUCT research team, rather than at the end of the study period; this will include all completed copies of questionnaires and all paperwork relevant to the Best Practice Tool.
- Staff sickness records for the TMCD will be collated and reported to the AQUEDUCT research team at baseline and at the 6 month follow-up point for the preceding time period (6 months duration each).
- Practitioners in all TMCDS, those in the intervention arm and those in the control arm, will identify a sample of people with dementia (where possible) or carers (to a total of n = 240 across all 24 TMCDs [17]) to complete individually secondary outcome measure questionnaires (CSQ-8, ED-5Q-5L, GHQ-12).

<u>Procedure for People with Dementia</u>:

- If recruitment is possible (mental capacity allowing), a sample of people with dementia (to a total of n = 240 across all 24 TMCDs) will complete a Client Satisfaction Questionnaire (CSQ-8) once post discharge from the TMCD; this will take into account TMCDs taking part in both the intervention arm and the control arm of the trial.
- If recruitment is possible (mental capacity allowing), the same sample of people with dementia from both the intervention arm and the control arm (to a total of n = 240 across all 24 TMCDs) will complete a Quality of Life Questionnaire (EQ-5D-5L) once post discharge from the TMCD.
- Again if recruitment is possible (mental capacity allowing), the same sample of people with dementia from both the intervention and control arms (to a total of n = 240 across all 24 TMCDs) will complete a General Health Questionnaire (GHQ-12) once post discharge from the TMCD.
- *All measures can be completed <u>up to 6 weeks post discharge</u> of the person with dementia from the TMCD*.

Procedure for Carers:

- A sample of carers of people with dementia (combining with above sample, to a total of n = 240 across all 24 TMCDs) will complete a Client Satisfaction Questionnaire (CSQ-8) once post discharge from the TMCD; this will take into account TMCDs taking part in both the intervention arm and the control arm of the trial.
- The same sample of carers from both the intervention arm and the control arm (combining with above sample, to a total of n = 240 across all 24 TMCDs) will complete a Quality of Life Questionnaire (EQ-5D-5L) once post discharge from the TMCD.
- The same sample of carers from both the intervention and control arms (combining with above sample, to a total of n = 240 across all 24 TMCDs) will complete a General Health Questionnaire (GHQ-12) once post discharge from the TMCD.
- *All measures can be completed up to 6 weeks post discharge of the person with dementia from the TMCD*.

The following table outlines specific task responsibilities regarding measures and data collection during this RCT (WP3.1):

Information Covered	Measure/Data Collection	Action
NHS Trust and TMCD initial screening	Screening to include: • NHS Trust and TMCD eligibility, including ability to collate and report psychiatric hospital admissions data, and to provide details of local acute NHS Trust(s) relevant to TMCD geographical catchment area • TMCD's agreement to complete research activities • TMCD contact details • Record of TMCD volunteer 'research co-ordinators' • Details of COVID-19 restrictions in local area	Responsibility of AQUEDUCT research team
Post-training Self-administered Assessment on the RK	• Assessment of understanding post RK training, completed by TMCD practitioners	Responsibility of AQUEDUCT research team
Hospital admissions for people with dementia to mental health beds, in the geographical catchment area of the TMCD (as defined by postcode)	• *Psychiatric hospital admissions in TMCD catchment area* – to be collated and reported at baseline and 6 month follow-up point for preceding time period (6 months duration each)	Records to be maintained and reported by NHS Trust R&E Department covering TMCD
Hospital admissions for people with dementia to acute beds, in the geographical catchment area of the TMCD (as defined by postcode)	• *Acute/general hospital admissions in TMCD catchment area* – to be collected at baseline and 6 month follow-up point for preceding time period (6 months duration each)	Precise details of local acute NHS Trust(s) relevant to TMCD geographical catchment area to be provided by NHS Trust R&E Department covering TMCD; subsequent data collection will be responsibility of AQUEDUCT research team
Assessment of satisfaction with service input received by people with dementia and carers, measured using a standardised scale	• Client Satisfaction Questionnaire (CSQ-8) – completed once post discharge from the TMCD, to a total n = 240 across all 24 TMCDs NB – people with dementia (where possible) and carers can complete measure up to 6 weeks post discharge from TMCD	CSQ-8 to be completed once post discharge from the TMCD (to a total n = 240 across all 24 TMCDs) by people with dementia (where possible) and carers identified by TMCD practitioners; responsibility of TMCD research co-ordinators

Assessment of quality of life of people with dementia and carers, measured using a standardised scale	• Quality of Life Questionnaire (EQ-5D-5L) – completed once post discharge from the TMCD, to a total n = 240 across all 24 TMCDs NB – people with dementia (where possible) and carers can complete measure up to 6 weeks post discharge from TMCD	EQ-5D-5L to be completed once post discharge from the TMCD (to a total n = 240 across all 24 TMCDs) by people with dementia (where possible) and carers identified by TMCD practitioners; responsibility of TMCD research co-ordinators
Assessment of general health of people with dementia and carers, measured using a standardised scale	• General Health Questionnaire (GHQ-12) – completed once post discharge from the TMCD to a total n = 240 across all 24 TMCDs NB – people with dementia (where possible) and carers can complete measure up to 6 weeks post discharge from TMCD	GHQ-12 to be completed once post discharge from the TMCD (to a total n = 240 across all 24 TMCDs) by people with dementia (where possible) and carers identified by TMCD practitioners; responsibility of TMCD research co-ordinators
Assessment of work acceptance and action by TMCD practitioners, measured using a standardised scale	• Work Acceptance & Action Questionnaire (WAAQ) – completed by all TMCD practitioners at baseline and at 6 month follow-up point	WAAQ to be completed individually by all practitioners in TMCD; responsibility of TMCD research co-ordinators
Assessment of work engagement by TMCD practitioners, measured using a standardised scale	• Utrecht Work Engagement Scale (UWES) – completed by all TMCD practitioners at baseline and at 6 month follow-up point	UWES to be completed individually by all practitioners in TMCD; responsibility of TMCD research co-ordinators
Assessment of general health of TMCD practitioners, measured using a standardised scale	• General Health Questionnaire (GHQ-12) – completed by all TMCD practitioners at baseline and at 6 month follow-up point	GHQ-12 to be completed individually by all practitioners in TMCD; responsibility of TMCD research co-ordinators
Assessment of sickness absence for TMCD practitioners	• TMCD practitioner sickness absence to be collated for all TMCD practitioners at baseline and at 6 month follow-up point for preceding time period (6 months duration each)	TMCD practitioner sickness absence to be collated and reported by TMCD research co-ordinators
Best Practice Tool scores for TMCDs in the intervention arm across the duration of the study period	• BPT – completed by TMCDs in intervention arm only at baseline and at 6 month follow-up point	BPT to be completed as a joint exercise by members of TMCD; responsibility of TMCD research co-ordinators
Measures for analyses of costs associated with use of the RK by TMCDs	• Hospital admissions data, above • EQ-5D-5L questionnaire, above Additionally: • For intervention arm only, activity records completed by	Hospital admissions data and EQ-5D-5L, as above. Activity records and care home admissions records completed throughout for

	TMCD, to monitor time spent implementing the Resource Kit in practice • For intervention arm only, support elements *e.g*. weekly contact (*via* multimedia means, telephone call or email) monitored by AQUEDUCT research team, to identify usage and costs • For both study arms, records of i) number of permanent care home admissions, ii) number of respite care admissions kept throughout by TMCD	TMCD; responsibility of TMCD research co-ordinators. Records of support required when using RK completed throughout for TMCD; responsibility of AQUEDUCT research team

Duration

Overall involvement in the RCT will be for approximately 8 months, to include provision of backdated hospital admissions data from all NHS Trusts, initial set-up for all TMCDs, delivery of all participant-completed measures, and completion of the BPT for those TMCDs participating in the intervention arm before and after implementation of the Resource Kit; TMCDs in the intervention arm will implement the Resource Kit for 6 months and TMCDs in the control arm will deliver TAU for 6 months.

WP3.2: Qualitative Evaluation of the Experience of Using, or Receiving Input from a TMCD Using, the Resource Kit

Aim

To complete questionnaires with TMCD practitioners, and semi-structured interviews with people with dementia and carers, on their experience of using, or receiving input from the TMCD using, the Resource Kit.

Design

Study-specific questionnaires will be completed by 36 TMCD practitioners from the intervention arm of the RCT, and semi-structured interviews, to be conducted remotely, will be completed with 12 people with dementia or carers who received input from a TMCD which participated in the intervention arm of the RCT.

Recruitment

Purposive sampling will be carried out to ensure that individuals are recruited who have diverse experience and perspectives. TMCD practitioners will be identified and approached by a member of the AQUEDUCT research team who will ask if they will consider participation. All people with dementia and carers will be identified and approached initially by a TMCD practitioner who will ask if they are happy to be contacted by a member of the AQUEDUCT research team. For people with dementia and carers, it will be emphasised that participants will be supported through semi-structured interviewing to verbalise their own account of their own experience of receiving input from a TMCD which used the Resource Kit during the RCT.

Sample

TMCD practitioner questionnaires will involve 36 purposively sampled practitioners from the intervention arm of the RCT.

Person with dementia and carer interviews will involve 12 individuals from the intervention arm of the RCT.

For both qualitative elements together, there will be a total of 48 participants.

Procedures

Prior to completion of the TMCD practitioner questionnaires, a member of the AQUEDUCT research team will distribute the relevant information sheet (Appendix 7), answer questions, give potential participants up to 3 days to decide whether or not they wish to be involved, and take written consent (Appendix 8) from all those who wish to be involved. The study-specific questionnaire to be completed will explore practitioner perspectives on their experience of using the Resource Kit, relevant to engagement, usefulness, barriers and facilitators of implementation.

For the person with dementia or carer, the semi-structured interview will be conducted while they are in their own home, to ensure the person with dementia or carer feels as comfortable as possible and can talk freely. The interview will explore the participant's experience of receiving input from a TMCD which used the Resource Kit during the RCT. Following initial contact by a member of the TMCD, if the potential participant is interested, a member of the AQUEDUCT research team will provide the relevant information sheet (Appendix 9 or 10), answer any questions, give potential participants up to 3 days to decide whether or not they wish to be involved, and take written consent (Appendix 11) from the person with dementia or carer if they wish to be involved. The interview will then take place remotely with a member of the AQUEDUCT research team, *via* multimedia means or by telephone, whichever is preferred by the participant; this will also allow for any possibility that the participant may be in quarantine or in a period of lockdown because of COVID-19. Any cost incurred *e.g*. the cost of a telephone call, will be met by the AQUEDUCT research programme. If practically possible, the interview will be recorded for the purpose of transcription only; this recording will be deleted when the transcription is completed.

The following table outlines specific task responsibilities regarding data collection during WP3.2:

Information Covered	Data Collection	Action
TMCD Practitioner Experience	• Questionnaire on practitioner experience of using the RK	Responsibility of AQUEDUCT research team
Person with Dementia and Carer Experience	• Semi-structured interview with person with dementia or carer on experience of receiving practitioner input from a TMCD using the RK	Responsibility of AQUEDUCT research team

Duration

Questionnaires – approximately 10 minutes to complete, for each participant.

Interviews – approximately 30 minutes, for each participant.

6.3 Participant Involvement

- Members of the AQUEDUCT research team will identify and approach potential managers or appropriate senior practitioners who work in a TMCD.
- TMCD managers or appropriate senior practitioners will then identify other TMCD practitioners.
- People with dementia and carers will be approached by a practitioner from their own TMCD.
- All potential participants will be given information about the study *via* participant information sheets, (all in Appendices). All potential participants will have opportunity to ask questions and will be given time to consider whether or not they wish to participate, before they are asked to sign the relevant consent form (all in Appendices) if they wish to be involved. Participation is voluntary.
- Participant recruitment will only begin when all appropriate confirmations (Research Ethics Committee (REC), Health Research Authority (HRA), and NHS Trust Research and Evidence Department (R&E)) are in place. Recruitment for this study (WP3) is expected to begin late autumn 2020.
- The duration of participants' involvement will depend on the research stage to which they are recruited. For each stage of the research, potential participants will be given a separate information sheet and asked to give consent for participation in that particular research stage only.
- In the RCT (WP3.1), overall duration will be approximately 8 months, to include provision of backdated hospital admissions data from all NHS Trusts, initial set-up for all TMCDs, delivery of all participant-completed measures, and completion of the BPT for those TMCDs participating in the intervention arm before and after implementation of the Resource Kit; TMCDs in the intervention arm will implement the Resource Kit for 6 months and TMCDs in the control arm will deliver TAU for 6 months.
- For the qualitative data collection (WP3.2), questionnaires will take approximately 10 minutes for each participant to complete (for TMCD practitioners), and semi-structured interviews will take approximately 30 minutes for each participant to complete remotely (for people with dementia and carers).

6.4 Participant Recruitment and Consent

The outlines, locations and research activities for each stage of this study are presented above in the separate research design sections.

Recruitment of TMCD Practitioners – WP3.1

For the RCT (WP3.1), TMCD managers whose team practitioners are potential participants will be approached by a member of the AQUEDUCT research team. Once the relevant NHS Trust has agreed formally to participate in this research, each TMCD manager or appropriate senior practitioner will receive an information pack which will include an information sheet for potential practitioner participants (Appendix 1). The TMCD manager or appropriate senior practitioner will identify 2 practitioners who can act as volunteer 'research coordinators' for their TMCD, and these practitioners will be given up to 3 days from receiving the study information to decide if they wish to participate. A site set-up visit from the AQUEDUCT research team will then take place, during which occasion copies of the information sheet (Appendix 1) and consent form (Appendix 2) will be reviewed, opportunity for questions given, and consent taken from those TMCD practitioners who wish to act as research coordinators as they themselves will be subject to data collection. From this point on, it will be the responsibility of the TMCD research coordinators to arrange and confirm consent with their fellow TMCD practitioners, following the procedure (to include the time allowance of 3 days for consideration) used for confirmation of their own consent. This delegation of responsibility will be recorded formally in the Site Delegation Log (Appendix 3).

Recruitment of People with Dementia and Carers – WP3.1

For the RCT (WP3.1), people with dementia (where possible, mental capacity allowing) and carers will be recruited on an ongoing basis as they are referred onto the TMCD caseload. People with dementia and carers will be approached by a TMCD practitioner who will give them the appropriate information sheet (Appendix 4 or 5) and explain to them that their particular TMCD has agreed to participate in the AQUEDUCT research programme; so they are being invited to participate in the research also. They will be given up to 3 days to decide if they wish to participate. On first contact with the person with dementia, and at every subsequent meeting with the person with dementia, the TMCD practitioner will determine the mental capacity (according to the Mental Capacity Act 2005) of the person with dementia to give informed consent to take part in the research. Opportunity will be given to ask questions and consent will then be taken (Appendix 6) from the person with dementia. A consent form will be completed separately with the carer regarding their own involvement in the RCT (Appendix 6).

Recruitment of TMCD Practitioners – WP3.2

For the questionnaires to evaluate experience of using the Resource Kit (WP3.2), TMCD practitioners will be identified and approached by a member of the AQUEDUCT research team who will ask if they will consider participation. Potential participants will be given the relevant information sheet (Appendix 7); the research will be explained to them verbally, and potential participants will have opportunity to ask questions and will be given up to 3 days to decide whether or not they wish to participate in advance of consent giving (Appendix 8).

Recruitment of People with Dementia and Carers – WP3.2

For their 'experience' interviews (WP3.2), people with dementia and carers will be approached initially by a member of the TMCD who will ask if they would be happy to speak to a member of the AQUEDUCT research team. All potential participants will then be given the relevant information sheet (Appendix 9 or 10); the research will be explained to them verbally, and potential participants will have opportunity to ask questions and will be given up to 3 days to decide whether or not they wish to participate in advance of consent giving (Appendix 11).

7 Participation Eligibility Requirements

7.1 Inclusion Criteria

WP3.1: Randomised Controlled Trial of the Resource Kit

- Teams managing mental health crises in dementia in community settings, and practitioners, people with dementia and carers associated with these TMCDs**.**

WP3.2: Qualitative Evaluation of the Experience of Using, or Receiving Input from a TMCD Using, the Resource Kit

- Practitioners completing a questionnaire will be purposively selected from TMCDs which have participated in the intervention arm of the RCT.
- People with dementia participating in a remote, semi-structured interview will (1) have a diagnosis of dementia, (2) have received input within the previous 6 weeks from a TMCD which has participated in the intervention arm of the RCT, and (3) be able to report on the input they received.
- Carers participating in a remote, semi-structured interview will have provided support for a person with dementia who has received input within the previous 6 weeks from a TMCD which has participated in the intervention arm of the RCT.

7.2 Team Exclusion Criteria

TMCDs will be excluded for the following reasons:

- Team is not defined by service/NHS Trust as having a role in dementia mental health crisis management.
- Team does not meet the following definition for mental health crisis: *providing urgent mental health assessment and intervention for people with dementia in the community*.
- A major service reorganisation is planned over the study period, or is anticipated in the near future.
- NHS Trust and team are not able to demonstrate capacity and capability to complete required research activities.
- Team is co-located with another team taking part in this study; sharing the same site is acceptable but sharing the same office is not.
- Team shares immediate management structures with another team taking part in this study; sharing a management structure above the level of team leader is acceptable but sharing a team leader is not.
- Core clinical staff for team do not operate separately from another team taking part in this study; this includes a requirement that core clinical staff must not engage in clinical cross cover with another team taking part in this study.
- Team shares core administrative staff with another team taking part in this study.
- If a team leader who has been exposed to the intervention becomes lead for a team in the control arm of the RCT, that latter team will then be excluded.

7.3 Expected Participant Duration

- In the RCT (WP3.1), overall involvement will be for approximately 8 months, to include provision of backdated hospital admissions data from all NHS Trusts, initial set-up for all TMCDs, delivery of all participant-completed measures, and completion of the BPT for those TMCDs participating in the intervention arm before and after implementation of the Resource Kit; TMCDs in the intervention arm will implement the Resource Kit for 6 months and TMCDs in the control arm will deliver TAU for 6 months.
- For the qualitative data collection (WP3.2), questionnaires will take approximately 10 minutes for each participant to complete (for TMCD practitioners), and semi-structured interviews will take approximately 30 minutes for each participant to complete remotely (for people with dementia and carers).

7.4 Informed Consent

For all participants (people with dementia, carers, and TMCD practitioners) across both sections of WP3 (WP3.1 and WP3.2), informed consent will be obtained in the following way:

Potential participants will be –

- given information sheets prior to participation,
- fully informed about the particular research activity in which they may participate, and the potential risks and benefits of taking part in this research,
- informed that participation is voluntary,
- given opportunity to ask questions and given up to 3 days to decide whether or not they wish to participate.

If after this they do wish to be involved, participants will be asked to sign the relevant consent form, (all in Appendices). Participants will also be informed that they can withdraw at any point and will be given information on how to do this. It will be made clear to all potential participants that a decision to participate or otherwise will not impact on their current or future work within clinical services or use of clinical services.

7.5 Participant Withdrawal

Participants will be withdrawn from the research if their consent is withdrawn. The participant information sheets and consent forms (all in Appendices) will inform participants of their right to withdraw from the research for any reason (which does not need to be stated) and at any time, without any effect on their employment (for TMCD practitioners) or input from services (for people with dementia and carers).

Participants may be withdrawn if they do not complete the research activities.

8 Research Measures and Data

8.1 Analysis and Evaluation

8.1.1 Sample size and justification

The sample size calculation was based on scoping information collected in earlier stages of the AQUEDUCT research programme, which showed the average hospital admission count *per* TMCD catchment area over a 6 month period to be 33. Following consultation with stakeholders, it was agreed that a 20% reduction represented the minimum clinically important difference (MCID); therefore, 12 TMCDs will be required in each of the two study arms (24 in total) to detect a 6.5 point mean admission count difference between arms with 80% power at a two-tailed 0.05 significance level [18], assuming the count of hospital admissions follows a Poisson distribution. It is anticipated that no TMCD will withdraw from the study and that NHS Trusts will provide the required hospital admissions data for each TMCD; thus, it is unlikely that the number of TMCDs required will be influenced by lost information due to TMCD withdrawal. Software Stata 16 was used for this power analysis.

8.1.2 Adherence and protocol deviations

Compliance will be assessed based on adherence to use of the Resource Kit as directed in this protocol by TMCDs in the intervention arm, and adherence to study support procedures as directed in this protocol by all participating TMCDs.

It will be defined as:

1. Completion of the Best Practice Tool (from the Resource Kit) by TMCDs in the intervention arm so that a score out of 100 is generated and communicated to the AQUEDUCT research team, at both baseline and follow-up time points.
2. Uptake by TMCDs in the intervention arm of the required number of templates and/or documents (four) from the Resource Kit.
3. Continued use by TMCDs in the intervention arm of the required number of templates and/or documents (four) from the Resource Kit for the full study duration (six months).
4. For TMCDs in both the intervention arm and control arm, participation in weekly contact with the AQUEDUCT research team for the full study duration (six months).

Descriptive statistics on percentage compliance will be summarised by group.

The following are pre-defined protocol violations with a direct bearing on the primary outcome: non-adherence to items numbered 1, 2 and 3 in above list. Protocol deviations will be classified prior to unblinding. The number (and percentage) of TMCDs with protocol deviations will be summarised by group with details of type of deviation provided. No formal statistical testing will be undertaken.

8.1.3 Statistical methods

The data analysis will be conducted on an Intention to Treat (ITT) basis. Exploratory analysis will be conducted firstly for all outcomes and all subject background variables. Descriptive statistics for each variable will be presented separately at both baseline and follow-up, with means (and SDs) for normally distributed variables, medians (IQRs) for skewed variables, and frequencies (percentages) for each level of categorical variable.

Poisson regression with binary arm status as an explanatory variable will be implemented to quantify the treatment effect estimates and precision on hospital admission; an over-dispersion check will be performed and a negative binomial regression model will be used if there is evidence that the outcome variance is greater than the mean. Treatment effect estimates on individual TMCD practitioner, person with dementia and carer outcome measures will be explored *via* multilevel modelling (MLM), with the TMCD as the level two analytical unit; baseline measures will be included as covariates [19, 20]. Skewed continuous outcome variables will be transformed for MLM, and nonlinear MLM will be performed for categorical outcomes.

No interim analysis is planned, and safety and adverse event information will be presented descriptively. All analysis will be backed up to the University of Nottingham (UoN) servers. Data will be analysed by the trial statistician who will be blinded for allocation status during final analysis and led by Chief Investigator Professor Martin Orrell, with support from other members of the AQUEDUCT Trial Management Group (TMG). The statistical analysis will be conducted using the most current version of Stata software or other appropriate analysis software. The trial statistical analysis plan (SAP) documenting full details of each proposed analytical procedure will be in place before the trial data are locked for the blinding review.

8.1.4 Procedures for missing, unused and spurious data

Missing values will be checked and reported across both arms for all outcome measures collected for all participant groups. For the primary outcome psychiatric hospital admissions information, as NHS Trusts will provide the data, it is unlikely there will be any missingness. For secondary outcomes collected from people with dementia, carers and TMCD practitioners, multilevel logistic regression will be used to explore the influence of group status and baseline measures on outcome data absence with the TMCD as the level two analytical unit. These results will be used to inform missing value imputation using analytical modelling under missing at random (MAR) assumptions [21, 22]; Stata and REALCOM software will be used to perform multiple imputations.

8.1.5 Costings analysis

A cost-consequences, cost-effectiveness and cost-utility analysis of the AQUEDUCT intervention will be undertaken. Costs information will be collected using a 'reduced list' approach to costing [23], reflecting the necessary adaptation of methodology required following the COVID-19 pandemic. This will avoid use of expensive-to-collect items of data which are unlikely to vary between the intervention arm and treatment as usual (TAU) arm, such as GP costs which are unlikely to affect overall cost differences. Key cost items will include hospital in-patient care (both acute and mental health beds), care home admissions involving TMCDs, staff mix, and mental health team inputs and other resources employed by teams in support care packages such as day care and respite care. Key sources for cost data will be team records and administrative data rather than the Client Service Receipt Inventory (CSRI) [24] or Resource Utilisation in Dementia (RUD) tool [25, 26], reflecting the necessary adaptation of methodology. These service use data will be collected for each participant. Each item of resource use will be multiplied by the unit cost specific to that item, using national unit costs published at the time of analysis.

A cost-consequences analysis (CCA) will be undertaken, laying out a comprehensive list of costs, including service use and trial outcomes (hospital admissions and quality of life measures). Bootstrapping will be used to generate incremental cost-effectiveness ratios and plot cost-effectiveness acceptability curves (CEACs). A cost-effectiveness analysis (CEA) will be undertaken, examining comprehensive service use costs (using national cost measures) and comparing these with changes in the primary outcome measure. Sensitivity analyses will also be conducted to address policy issues of where services might be most cost-effectively targeted in future and the implications of variations in team staff case-mix upon outcomes.

The primary economic evaluation will be a cost-utility analysis (CUA) from an NHS and personal social services (PSS) perspective based on the within-trial period. A cost *per* QALY (Quality-Adjusted Life Year) will be calculated for people with dementia and for carers. QALYs gained from baseline to end of scheduled follow-up will be estimated as the number of weeks multiplied by the utility of observed survival. The utility values will be estimated from the EuroQol EQ-5D-5L health status questionnaire completed at follow-up and the associated published societal utility tariffs. Multiple imputation and censored data analysis techniques will be used to impute separately missing data due to missing observations both in participants who complete follow-up and those who do not. The primary analysis will be treatment allocated, controlled for key baseline covariates or characteristics.

8.2 Participant Sample Size

WP3.1: Randomised Controlled Trial of the Resource Kit

TMCD practitioners (total approx. 144) and people with dementia or carers (total approx. 240) from 24 TMCDs will be recruited. *Overall total 384*.

WP3.2: Qualitative Evaluation of the Experience of Using, or Receiving Input from a TMCD Using, the Resource Kit

36 study-specific questionnaires will be completed by purposively sampled TMCD practitioners (3 *per* TMCD) from the intervention arm only. A total of 12 semi-structured interviews (conducted remotely) will be completed with purposively sampled people with dementia or carers from across TMCDs participating in the intervention arm only. *Overall total 48*.

Overall participant contacts: 432 participants (TMCD practitioners: 180; people with dementia and carers of people with dementia: 252).

9 Trial Supervision

The following groups have been established to oversee the trial.

9.1 Trial Steering Group (TSG)

The Trial Steering Group (TSG) will meet during set-up and thereafter at least annually. Additional meetings may be called by the Chief Investigator (CI) should additional advice on trial conduct or management be required.

Membership of the TSG will be approved by NIHR, the trial funders. The TSG will include an independent Chair, at least two independent members with appropriate methodological and clinical expertise, one or two patient and public involvement (PPI) representatives (a person with dementia or carer), and the CI and other relevant members of the Trial Management Group (see below). Representatives from NIHR and from the trial sponsor (Nottinghamshire Healthcare NHS Foundation Trust) may also attend TSG meetings as active members.

The role of the TSG will be to:

- Advise the Chief Investigator on all aspects of the trial.
- Provide overall supervision of the trial protocol, case report form, and statistical analysis.
- Monitor trial progress.
- Review relevant information from other sources related to the trial.
- Review outputs and final reports.
- If necessary, prematurely close the trial.

9.2 Data Monitoring Committee (DMC)

The Data Monitoring Committee (DMC) will meet on two to three occasions (or more often if necessary), and will consist of a Chair, a statistician and a clinical researcher. Membership of the DMC will be approved by the funding body, NIHR. Members of the DMC will be independent of the trial.

The role of the DMC will be to:

- Review the trial protocol with regard to issues of data management and analysis.
- Review the protocol and study materials, pertinent to their duties as the DMC.
- Advise the TSG when it believes the trial protocol should be altered.
- Advise the TSG if the committee feels the trial should be prematurely closed.

9.3 Trial Management Group (TMG)

The Trial Management Group (TMG) is accountable to the TSG for the implementation of the trial. The TMG will meet on a monthly basis during the set-up of the trial and then monthly or bimonthly, as appropriate. It will consist of key individuals directly involved in the development and delivery of the trial. This will include the Chief Investigator, the Trial Manager, collaborators, and experts by experience. For membership details of the TMG, please see page 8.

The role of the TMG will be to:

- Monitor trial progress, to ensure compliance with and adherence to the project plan.
- Identify and resolve issues on the intervention and associated research in a timely manner.
- Consider and act on recommendations of the TSG and Research Ethics Committee.

9.4 Programme Management Group (PMG)

The PMG comprises the Chief Investigator, all collaborators, researchers, and PPI representatives involved in the AQUEDUCT programme. It is not directly related to the conduct of the trial as such, but it will continue to meet every 6 months to review the progress of the programme as a whole.

10 Adverse Events

There is a minimal risk that people with dementia, carers and TMCD practitioners may become distressed while completing semi-structured interviews and questionnaire assessments. For people with dementia and carers, this distress will be distinguished from distress experienced during a mental health crisis; participants will be asked to indicate that the distress is caused by the research activities. No other adverse events are anticipated. All adverse events will be recorded in the case report form (CRF) (Appendix 12). Participants will be informed that they can cease participation at any time without any impact on their employment or clinical input.

11 Regulatory Aspects

11.1 Ethical and Other NHS Approvals

All relevant confirmations will be sought prior to commencing research at any site (REC; HRA; R&E assessment and confirmation of capacity and capability). No amendments will be made to the research protocol or study documentation (participant information sheets or consent forms) without approval from the relevant bodies (HRA, NHS Trust sponsor). The study will be conducted in accordance with ethical principles based on the UK Policy Framework for Health and Social Care Research [27], the Mental Capacity Act 2005 [28], Good Clinical Practice (GCP) [29], and the Declaration of Helsinki [30]. All correspondence with the HRA will be retained.

If an accidental protocol deviation occurs, this will be clearly documented on the protocol deviation form in the CRF (Appendix 12) and reported to the Chief Investigator (CI) and NHS Trust sponsor immediately. Deviations from the protocol that are found to recur frequently are not acceptable and will require immediate action.

The CI will submit an annual progress report to NIHR within 30 days of the anniversary date on which grant approval was given, until the AQUEDUCT research programme is declared ended. At the end of the AQUEDUCT research programme, the CI will submit a final report with results to NIHR.

11.2 Deception

This study does not involve use of deception. Participants will be informed about each research activity verbally and given the relevant printed information sheet (all included in Appendices) prior to participating in each stage of the research. No debrief will be necessary as participants will be fully informed throughout the research process.

11.3 Consent

Informed consent will be obtained from all participants for each stage of the study; details of the processes for consent at each stage of the research are outlined in earlier sections of this protocol.

In summary, potential participants will be:

- given information sheets prior to participation,
- fully informed about the particular research activity in which they may participate, and the potential risks and benefits of taking part in this research,
- informed that participation is voluntary,
- given opportunity to ask questions and given up to 3 days to decide whether or not they wish to participate.

It will be made clear to all potential participants that any decision they take to participate or otherwise will not impact on their current or future work within clinical services or use of clinical services. All participants will be asked to consent separately, by signing the relevant consent form, to each stage of the research with which they wish to engage. They will be informed that they can withdraw at any point and will be given information on how to do this.

11.4 Right to Withdraw

As indicated above, participants will be informed that their participation is voluntary and that they can withdraw from the study at any time. They can also withdraw their data; however, during analysis stages, in cases where anonymised data have been used, data withdrawal may not be possible as identifiable information will have been removed. Participants will be made aware of this on information sheets, prior to consenting.

11.5 Data Protection

All data will be treated in a confidential manner and the NHS Code of Confidentiality [31], General Data Protection Regulation (GDPR) [32], and GCP guidelines [29] will be adhered to. All research staff and practitioners involved in the study will be appropriately trained and supported with regards to the collection, storage, processing and disclosure of personal information.

All data will be ultimately managed in a systematic and verifiable process and limited to the AQUEDUCT research team. All data will be used only for the purposes of research set out in the participant information sheets and in this protocol. No participant will be identifiable in any of the research outputs.

Each participant will be assigned a unique identification code (whereby the participant's identifying information will be replaced by an unrelated sequence of characters) that will be used for all research

data and storage systems. The AQUEDUCT research team will hold a coding log for the anonymisation of study participants. Participants' identifiable information will be stored separately from the anonymised research data, and appropriate secure systems will be used: locked storage at the IMH which is itself a secure, restricted-entry building, and password protected and/or encrypted documents on password protected, secure computers. Personal data will only be accessible to the minimum number of individuals necessary for data analysis or audit. Only anonymised data will be transmitted to co-investigators at other sites. Non-personal data will be stored for 5 years after completion of the study in accordance with the terms of the Sponsor's contract with the funder (NIHR). Personal data will be stored for 3-6 months to allow completion of the research, and for results to be disseminated to participants who may wish this.

The CI Professor Martin Orrell will act as the data custodian for data generated by this research.

If a participant withdraws from this research, this will be recorded accordingly. Databases holding their details will be updated.

11.6 Vulnerable Groups

This research will include people with dementia. This research will therefore, adhere to the British Psychological Society's Guidance on Evaluation of Capacity to Consent [33], and consent will be seen as a continuing process. To accommodate the possibility that participants with dementia may lose the capacity to consent during this research, their willingness to participate will be continually checked throughout the process. Should a person lose the capacity to consent during the research period, the provisions of the Mental Capacity Act 2005 [28] will be followed.

11.7 Confidentiality

Individual participant information (personal or clinical) obtained as a result of this research will be considered as strictly confidential. Disclosure to third parties will be prohibited. Confidentiality will be protected through the use of unique identifiers as detailed in section 9.5 (above).

Data generated from this study may be liable for inspection on request by relevant bodies (Nottinghamshire Healthcare NHS Foundation Trust R&E Department, NHS Research Ethics Committee (REC), and IMH), and this fact will be indicated in the participant information sheets.

11.8 Indemnity

The sponsor's NHS indemnity will cover the design, conduct and management of the study. Each site will be required to provide their own indemnity which should be done *via* their own NHS indemnity.

Should any non-NHS sites be included in this study, such sites will also be required to provide their own indemnity cover.

11.9 Sponsor

Nottinghamshire Healthcare NHS Foundation Trust (NottsHC) is sponsor for this research and will fulfil this role by ensuring that good research governance is maintained throughout this study.

12 Funding

The NIHR Programme for Applied Research is funding this (now) 9 year research programme AQUEDUCT, grant number RP-PG-0612-20004. AQUEDUCT is a partnership between the University of Nottingham, Nottinghamshire Healthcare NHS Foundation Trust, University College London, University of East Anglia, City University of London, University of Hull, and University of Cambridge. The total funding is £2,092,766. All research costs will be covered by the NIHR research grant. The funder (NIHR) does not have any role in or control of the design, conduct, data analysis and interpretation, manuscript writing, or dissemination of this research. As an NIHR funded study, AQUEDUCT is eligible for adoption by the NIHR Clinical Research Network (CRN) Portfolio.

Participants will not receive payment for their involvement in this study; all participation is voluntary. For NHS staff participants, 'voluntary' is intended to mean that the NHS Trust which employs them will permit them to take part in the study during work time. People with dementia and carers will be reimbursed expenses (for example, for travel costs) that are wholly necessary and exclusive to involvement in this research, in which case they will be asked to complete an expenses claim form and to provide relevant receipts. Reimbursement will be at the standard NottsHC rates for service users and carers.

13 Patient and Public Involvement

In developing AQUEDUCT research proposals, the CI and Co-applicants extensively consulted with people with dementia, carers, and the voluntary sector through the earlier SHIELD research programme. This work involved focus groups about the causes of crisis and help needed in a crisis. People with dementia and carers were involved in a consensus process and consensus workshop, making decisions about the content and structure of the HTP which has informed the AQUEDUCT research programme.

'Patient and Public Involvement' (PPI) was integrated extensively throughout the qualitative data collection of Work Package 1 of the AQUEDUCT research programme, for example, PPI members were involved as co-facilitators of focus groups and acted as co-researchers alongside members of the AQUEDUCT research team, with involvement members and research staff working together to inform development of the Fidelity Measure and Resource Kit.

For WP2, a voluntary sector representative and a carer acted as members of the Programme Steering Group (PSG). The protocol for WP2 was developed in consultation with the AQUEDUCT PPI Reference Group and a Co-applicant on the grant application to NIHR (for funding for AQUEDUCT) who was able to draw on his own lived experience as a carer for a person with dementia.

The protocol for this present work package (WP3) was developed in consultation with the AQUEDUCT PPI Reference Group (as above) and an AQUEDUCT Clinical Staff Reference Group consisting of NHS practitioners currently working in TMCDs across England.

Significant funding is budgeted and made available for people with dementia, carers and voluntary sector staff for reimbursement of their time in PPI activities (using INVOLVE guidance and standard rates [34]). The cost of travel, meals and refreshments, time on staff interview panels, and conference participation is also covered.

14 Dissemination

Findings from WP1 informed development of the FM and Resource Kit used in the Feasibility Study in WP2, to maximise their suitability and usefulness for TMCDs working with people with dementia experiencing a mental health crisis, and carers, across England. In turn, the Feasibility Study informed the RCT in this present WP3. The AQUEDUCT research team will identify a variety of channels for dissemination to PPI representatives, research sites, and other key stakeholders. Findings will be relevant to healthcare professionals working with older people in settings where people with dementia and carers are likely to request support leading up to or during a crisis. This work may prove useful for service commissioners, other health and social care professionals, and researchers both nationally and internationally. Results from this study will be written up for suitable peer-reviewed journals and presented at relevant conferences and events. The Resource Kit will not be made available for widespread dissemination until the RCT has ended, in order to avoid contamination of sites seeking to participate in WP3; however, once the RCT is completed, a programme of implementation and long-term dissemination of the RK can begin. Participants can request a copy of results from the CI; this information will only be provided after the final study report has been completed. The funding body (NIHR) will be acknowledged in all forms of dissemination arising from this research.

15 Relevant Signatures

Chief Investigator:

Name: _Professor Martin Orrell_____

Signature: ___  _____

Date: ____21st October 2022_____

Sponsor Representative:

Name: _Mark Howells_____

Signature: _  _____

Designation: Head of Research & Evidence, Nottinghamshire Healthcare NHS Foundation Trust

Date: __10th November 2022_____

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17 Appendices

Appendix 1: for WP3.1

Participant Information Sheet A – for TMCD Practitioners Version 3 01.03.2021

1. **Research Study Title – Achieving Quality and Effectiveness in Dementia Using Crisis Teams (AQUEDUCT): A Randomised Controlled Trial of a Resource Kit for Teams Managing Crisis in Dementia**

2. **Name of Chief Investigator – Professor Martin Orrell**

3. **Invitation**

You are being invited to take part in a research study. Before you decide whether you would like to participate in the 'Achieving Quality and Effectiveness in Dementia Using Crisis Teams' (AQUEDUCT) study, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully, and ask us about anything that is unclear or if you require any further information. Please take time to decide whether or not you wish to participate in the study. Thank you for your time.

4. **What is the purpose of the study?**

The purpose of this AQUEDUCT study is to investigate the use of a Resource Kit in practice with Teams Managing Crisis in Dementia (TMCDs). The Resource Kit is for use by teams with people with dementia and their carers at times of crisis. This study looks at use of the Resource Kit in practice and related costs. The findings from this study will help us to evaluate how useful the Resource Kit has been.

5. **Why have I been invited to participate?**

You have been invited to participate because you are a member of a team which manages crises for people with dementia. We would like you to help us to evaluate the Resource Kit in practice; so that we can determine how useful the Resource Kit is for teams like yours. Practitioners from a number of other teams will also be recruited to this research.

6. **Do I have to take part?**

It is up to you to decide whether or not to take part. Taking part in this research is entirely voluntary. If you do decide to take part, you will be given this information sheet to keep and you will be asked to sign a consent form. You will still be free to withdraw at any time without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not adversely affect your job or your relationship with your manager. If at any point you wish to withdraw from the study, you may also withdraw your data; however, during analysis stages in cases where anonymised data have been used, data withdrawal may not be possible as any identifiable information will have been removed.

7. What will happen to me if I agree to take part?

A member of the AQUEDUCT research team, or one of the 'research coordinators' (see below), will start by explaining the purpose of the study, give you opportunity to ask any questions, and ask you to sign a consent form if you would like to take part in this research.

The study will involve identification of two volunteer 'research coordinators' from your team, to coordinate the research study within your team, to liaise with the AQUEDUCT research team, and to consent fellow team practitioners. The manager, the two practitioners identified as research coordinators, and an additional practitioner from the team will take part in an initial site set-up visit with the AQUEDUCT research team; this will involve giving consent to take part in the study and completing digital training. If your team has been assigned to the 'intervention arm,' which means your team will be using the Resource Kit, everyone in your team (if they have agreed to take part in the research) will complete a 'Post-training Self-administered Assessment' on the Resource Kit after the digital training, and the team will complete a Best Practice Tool review over the course of 2 weeks; the Best Practice Tool is part of the Resource Kit. For those teams taking part in the intervention arm, the team will use the Resource Kit for the duration of the study (6 months); all other teams will continue to work as usual for the 6 month study period.

You will be asked to complete 3 questionnaires at the start of the study and after 6 months. You will complete these assessments in person, not virtually. Your team will also let us know about staff sickness absence for the team during the study period. If your team is in the intervention arm, we will ask your team to re-complete the Best Practice Tool review at 6 months; your team will again have 2 weeks to do this on this occasion. We would like your team to return all paperwork (questionnaires and any materials used to complete the Best Practice Tool review) to us regularly on an ongoing basis, rather than at the end of the study.

In addition to the above, for the duration of your team's involvement in the study, the Research & Development Department for your NHS Trust and the AQUEDUCT research team will collect information about people with dementia who live in the catchment area for your team, who are admitted to hospital. This will not involve direct action on your part or by anyone from the team in which you work, but we want you to know that this will be happening.

8. What are the possible disadvantages and risks of taking part?

If you choose to take part, you will be contributing to a National Institute for Health Research (NIHR) study. The AQUEDUCT research team considers there to be minimal disadvantages to participating in this study.

9. What are the possible benefits of taking part?

There will be no immediate benefits to you for taking part in this study; however, you may be introduced to some new ideas about best practice for crisis teams who manage dementia. The AQUEDUCT research team cannot promise that the study will help you directly, but the information obtained from this study may help to improve the work of crisis teams in the future.

10. What if something goes wrong?

If you have a concern about any aspect of this study, you should ask to speak to one of the researchers who will do their best to answer your questions. The AQUEDUCT research team's contact details are given at the end of this information sheet.

If you would like to speak to someone about any other issues raised for you during the course of the study, or to make a complaint, please contact:

_____
_____
_____
_____

11. How will we use information about you?

We will need to use information from you for this research project. This information will include:

- your name
- your contact details

People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

12. What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

13. Where can you find out more about how your information is used?

You can find out more about how we use your information:

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from www.hra.nhs.uk/information-about-patients/research
- by asking one of the research team
- by sending an email to DPOEnquiries@nottshc.nhs.uk
- or by ringing us on 0115 7484323 (AQUEDUCT administrator's number).

14. What will happen to the results of the research study?

Results from this study will inform use of the Resource Kit by teams working with people with dementia and their carers in crises, and if successful, it will support other teams nationwide. If you would like to know the results, please tell the AQUEDUCT research team and they will send you a summary. Great care will be taken to ensure that no identifiable participant information will be used in the results and all such information will be kept as strictly confidential.

15. Who is organising and funding the research?

The research is funded by the Department of Health and Social Care's National Institute for Health Research. The research study is led by Professor Martin Orrell, who is Director of the Institute of Mental Health, Nottingham.

16. Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee. Research Ethics Committees safeguard the rights, safety, dignity and well-being of people participating in research in the National Health Service. They review applications for research and give an opinion about the proposed participant involvement and whether the research is ethical. This study has been reviewed by such a Research Ethics Committee.

17. Contact for further information

Local site Principal Investigator:

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_____

_____

_____

OR

Dr Donna Maria Coleston
(Consultant Clinical Psychologist)
AQUEDUCT Project Manager
AQUEDUCT Research Team
Institute of Mental Health
Nottingham NG7 2TU
0115 7484323 (AQUEDUCT administrator's number)

Appendix 2: for WP3.1

Consent Form 1 – for TMCD Practitioners Version 3 01.03.2021

PARTICIPANT IDENTIFICATION CODE:

CONSENT FORM

Title of Study: **Achieving Quality and Effectiveness in Dementia Using Crisis Teams (AQUEDUCT) Main Trial**

Name of Chief Investigator: **Professor Martin Orrell**

Please initial all boxes

1. I confirm that I have read and that I understand information sheet A (version 3, dated 01.03.2021) for the above study. I have had opportunity to consider the information and to ask questions, and these questions have been answered satisfactorily. ☐

2. I understand that my participation is entirely voluntary and that I am free to withdraw at any time without giving any reason, without my legal rights being affected. ☐

3. I understand that sections of data collected during the study that are relevant to my participation may be looked at by individuals from regulatory authorities or from the NHS Trust sponsor. I give permission for these individuals to have access to these data. ☐

4. I understand that if I disclose something that indicates risk of harm to me or to others, the AQUEDUCT research team is obligated to inform the appropriate authorities. ☐

5. I agree to take part in the above study. ☐

_____	_____	_____
Name of participant	Date	Signature
_____	_____	_____
Name of person taking consent	Date	Signature

One copy for participant and one copy for investigator file

Appendix 3: for WP3.1

Site Delegation Log

Research Study: Achieving Quality and Effectiveness in Dementia Using Crisis Teams (AQUEDUCT): A Randomised Controlled Trial of a Resource Kit for Teams Managing Crisis in Dementia

Sponsor: Nottinghamshire Healthcare NHS Foundation Trust **Sponsor ID:** 127686/2020

Chief Investigator: Professor Martin Orrell, Institute of Mental Health, Nottingham

Funder: National Institute for Health Research (NIHR) Programme Grants for Applied Research **Grant Number:** RP-PG-0612-20004

Background:

The Principal Investigator (PI) at each site is responsible for the conduct of the research study, to ensure safety of participants and the reliability and robustness of all data generated. The signing of this form at each site stands as a declaration by the PI that they will abide by the responsibilities stated as part of the HRA approval process and the Research Governance Framework. The PI may delegate their duties according to the Site Delegation Log at their own discretion. This Site Delegation Log is used to record the responsibilities of the team at each site, authorised by the PI. It shows who is assigned a task and demonstrates that tasks are assigned appropriately, according to training and experience.

Purpose:

To ensure that members of the team understand the importance of the allocation of responsibilities and to clarify boundaries of responsibility for the management and conduct of the study.

Delegation Log Key

1. Coordinate approval communications/submissions
2. Screen/recruit study participants
3. Obtain informed consent
4. Confirm eligibility (inclusion/exclusion)
5. Perform study related assessments
6. Evaluate study related test results
7. Randomise study participants
8. Make CRF entries or corrections
9. Sign off CRFs
10. Resolve data queries
11. Maintain essential documents
12. Report AEs/SAEs
13. Activities related to regulatory communications/submissions
14. Activities related to randomisation code break

Site:

Name	Initials	Job Designation	Responsibilities for AQUEDUCT Study	Signature	Date	Authorising Signature and Name	Date Authorised
		.					

Appendix 4: for WP3.1

Participant Information Sheet B – Version for People with Dementia Version 3 01.03.2021

AQUEDUCT Study

AQUEDUCT stands for Achieving Quality and Effectiveness in Dementia Using Crisis Teams. We would like to invite you to take part in this research study.

What is the purpose of the study?

This study is about an online Resource Kit we have developed. The findings from this study will show us how useful the Resource Kit is when it is used by clinical teams who work with people with dementia who are experiencing a crisis.

Why have I been invited to take part?

We would like to ask you some questions about how life is for you at the moment and about your general health. We would like to know about this because you are using a team that works with people who have dementia and who are experiencing a crisis.

We would also like to ask you what you think about the team that is visiting you.

This information will help us to evaluate the Resource Kit that will support these teams and help them to provide the best care possible.

Do I have to take part?

It is up to you to decide whether or not to take part. Taking part in this study is entirely voluntary. If you decide to take part, you will be given this information sheet to keep and you will be asked to sign a consent form. You will still be free to withdraw at any time without giving a reason. The care you receive from the clinical team will not change if you do not take part in the study or if you withdraw from the study.

What will I have to do?

You will be given 3 questionnaires, and these will take about 20-30 minutes to complete in total. Everything you tell us will be kept as confidential. You can complete these questionnaires at a time and place that are convenient for you. You will complete these assessments in person, not virtually.

If there is a question that you do not want to answer, please do not worry. Deciding not to answer any questions will not have any effect on how you are treated by the team.

What are the possible risks or benefits of taking part?

We do not think there will be any risks involved in taking part in this study. There will be no immediate benefits to you for taking part; however, you may be introduced to some new ideas about good practice for crisis teams who work with people with dementia. The AQUEDUCT research team cannot promise that the study will help you directly, but the information we get may help to improve the work of crisis teams in the future.

What if something goes wrong?

We are not expecting anyone to become upset while answering these questions, but if you would like to talk to someone about any issues raised, or to make a complaint, please contact your local Patient Advice and Liaison Service (PALS). Here are their contact details:

_____
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How will we use information about you?

In this research study we will use information from you – we will use your name and your contact details. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study.

Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules.

At the end of the study we will save some of the data in case we need to check it. We will make sure no-one can work out who you are from the reports we write.

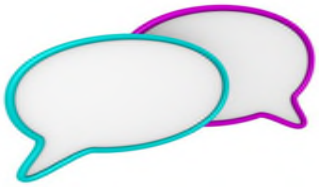
Please feel free to discuss this study with your family and friends before deciding whether to take part and if you have any questions, please ask us.

You can contact EITHER the local site Principal Investigator

_____
_____
_____
_____

OR

Dr Donna Maria Coleston
(Consultant Clinical Psychologist)
AQUEDUCT Project Manager
AQUEDUCT Research Team
Institute of Mental Health
Nottingham NG7 2TU
0115 7484323 (AQUEDUCT administrator's number)



Appendix 5: for WP3.1

Participant Information Sheet C – for People with Dementia and Carers

Version 3 01.03.2021

1. **Research Study Title – Achieving Quality and Effectiveness in Dementia Using Crisis Teams (AQUEDUCT): A Randomised Controlled Trial of a Resource Kit for Teams Managing Crisis in Dementia**

2. **Name of Chief Investigator – Professor Martin Orrell**

3. **Invitation**

You are being invited to take part in a research study. Before you decide whether you would like to participate in the 'Achieving Quality and Effectiveness in Dementia Using Crisis Teams' (AQUEDUCT) study, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully, and ask us about anything that is unclear or if you require any further information. Please take time to decide whether or not you wish to participate in the study. Thank you for your time.

4. **What is the purpose of the study?**

The purpose of this AQUEDUCT study is to investigate the use of a Resource Kit in practice with Teams Managing Crisis in Dementia (TMCDs). The Resource Kit is for use by the team with people with dementia and their carers at times of crisis. This study will look at use of the Resource Kit in practice and related costs. The findings from this study will help us to evaluate how useful the Resource Kit has been.

5. **Why have I been invited to participate?**

You have been invited to participate because you or a person you care for has had contact with a Team Managing Crisis in Dementia. We would like you to complete some paper questionnaires about satisfaction with the clinical team and about your own general health and quality of life. These 3 questionnaires will be completed once only, when you and/or the person you care for has been discharged from the team.

6. **Do I have to take part?**

It is up to you to decide whether or not to take part. Taking part in this research is entirely voluntary. If you do decide to take part, you will be given this information sheet to keep and you will be asked to sign a consent form. You will still be free to withdraw at any time without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not adversely affect your input from the clinical team. If at any point you wish to withdraw from the study, you may also withdraw your data; however, during analysis stages in cases where anonymised data have been used, data withdrawal may not be possible as any identifiable information will have been removed.

7. What will happen to me if I agree to take part?

The study will involve a practitioner from the Team Managing Crisis in Dementia explaining the purpose of the study and giving you the opportunity to ask any questions, before asking you to sign a consent form if you decide that you would like to take part in the research. **You will then be asked to complete 3 paper questionnaires about satisfaction with the clinical team and about your own general health and quality of life; these questionnaires will be completed once only, when you and/or the person you care for has been discharged from the Team Managing Crisis in Dementia. You will complete these assessments in person, not virtually.** Completion of these questionnaires should take no longer than 20-30 minutes.

8. What are the possible disadvantages and risks of taking part?

If you choose to take part, you will be contributing to a National Institute for Health Research (NIHR) study. The AQUEDUCT research team considers there to be minimal disadvantages to participating in this study.

9. What are the possible benefits of taking part?

There will be no immediate benefits to you for taking part in this study; however, you may be introduced to some new ideas about best practice for crisis teams who manage dementia. The AQUEDUCT research team cannot promise that the study will help you directly, but the information obtained from this study may help to improve the work of crisis teams in the future.

10. What if something goes wrong?

If you have a concern about any aspect of this study, you should ask to speak to one of the researchers who will do their best to answer your questions. The AQUEDUCT research team's contact details are given at the end of this information sheet.

If you would like to speak to someone about any other issues raised for you during the course of the study, or to make a complaint, please contact:

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11. What if my questionnaire responses suggest I need more support?

If your responses on the questionnaires suggest to us that you are experiencing difficulties, then we would like to help you to access support for this – we will speak to you about this, and we can contact your GP and/or the crisis team, to help you get the extra support you need. We would not be involved further than this, as we would like to keep your involvement in the research study separate from any clinical care that you may receive.

12. How will we use information about you?

We will need to use information from you for this research project. This information will include:

- your name
- your contact details

People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

13. What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

14. Where can you find out more about how your information is used?

You can find out more about how we use your information:

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from www.hra.nhs.uk/information-about-patients/research
- by asking one of the research team
- by sending an email to DPOEnquiries@nottshc.nhs.uk
- or by ringing us on 0115 7484323 (AQUEDUCT administrator's number).

15. What will happen to the results of the research study?

Results from this study will inform use of the Resource Kit by teams working with people with dementia and their carers in crises, and if successful, it will support other teams nationwide. If you would like to know the results, please tell the AQUEDUCT research team and they will send you a summary. Great care will be taken to ensure that no identifiable participant information will be used in the results and all such information will be kept as strictly confidential.

16. Who is organising and funding the research?

The research is funded by the Department of Health and Social Care's National Institute for Health Research. The research study is led by Professor Martin Orrell, who is Director of the Institute of Mental Health, Nottingham.

17. Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee. Research Ethics Committees safeguard the rights, safety, dignity and well-

being of people participating in research in the National Health Service. They review applications for research and give an opinion about the proposed participant involvement and whether the research is ethical. This study has been reviewed by such a Research Ethics Committee.

18. Contact for further information

Local site Principal Investigator:

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_____

_____

_____

OR

Dr Donna Maria Coleston
(Consultant Clinical Psychologist)
AQUEDUCT Project Manager
AQUEDUCT Research Team
Institute of Mental Health
Nottingham NG7 2TU
0115 7484323 (AQUEDUCT administrator's number)

Appendix 6: for WP3.1

Consent Form 2 – for People with Dementia and Carers Version 3 01.03.2021

PARTICIPANT IDENTIFICATION CODE:

CONSENT FORM

Title of Study: **Achieving Quality and Effectiveness in Dementia Using Crisis Teams (AQUEDUCT) Main Trial**

Name of Chief Investigator: **Professor Martin Orrell**

Please initial all boxes

1. I confirm that I have read and that I understand information sheet B or C (version 3, dated 01.03.2021) for the above study. I have had opportunity to consider the information and to ask questions, and these questions have been answered satisfactorily. ☐

2. I understand that my participation is entirely voluntary and that I am free to withdraw at any time without giving any reason, without my legal rights being affected. ☐

3. I understand that sections of data collected during the study that are relevant to my participation may be looked at by individuals from regulatory authorities or from the NHS Trust sponsor. I give permission for these individuals to have access to these data. ☐

4. I understand that if I disclose something that indicates risk of harm to me or to others, the AQUEDUCT research team is obligated to inform the appropriate authorities. ☐

5. I agree to take part in the above study. ☐

Name of participant	Date	Signature
Name of person taking consent	Date	Signature

One copy for participant and one copy for investigator file

Appendix 7: for WP3.2

Participant Information Sheet D – for TMCD Practitioners Version 3 01.03.2021

1. **Research Study Title – Achieving Quality and Effectiveness in Dementia Using Crisis Teams (AQUEDUCT): A Randomised Controlled Trial of a Resource Kit for Teams Managing Crisis in Dementia**

2. **Name of Chief Investigator – Professor Martin Orrell**

3. **Invitation**

You are being invited to take part in a research study. Before you decide whether you would like to participate in the 'Achieving Quality and Effectiveness in Dementia Using Crisis Teams' (AQUEDUCT) study, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully, and ask us about anything that is unclear or if you require any further information. Please take time to decide whether or not you wish to participate in the study. Thank you for your time.

4. **What is the purpose of the study?**

The purpose of this AQUEDUCT study is to investigate the use of a Resource Kit in practice with Teams Managing Crisis in Dementia (TMCDs). The Resource Kit is for use by teams with people with dementia and their carers at times of crisis. This study looks at use of the Resource Kit in practice and related costs. The findings and your feedback from this study will help us to evaluate how useful the Resource Kit has been.

5. **Why have I been invited to participate?**

You have been invited to participate because you work in a Team Managing Crisis in Dementia that agreed to take part in the AQUEDUCT study. We would like to ask for your feedback on using the Resource Kit during the study. This feedback is gathered at the end of your team's involvement in the research. Practitioners from a number of other Teams Managing Crisis in Dementia will also be asked their opinion about using the Resource Kit.

6. **Do I have to take part?**

It is up to you to decide whether or not to take part. Taking part in this research is entirely voluntary. If you do decide to take part, you will be given this information sheet to keep and you will be asked to sign a consent form. You will still be free to withdraw at any time without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not adversely affect your job or your relationship with your manager. If at any point you wish to withdraw from the study, you may also withdraw your data; however, during analysis stages in cases where anonymised data have been used, data withdrawal may not be possible as any identifiable information will have been removed.

7. What will happen to me if I agree to take part?

This part of the AQUEDUCT study will firstly involve a researcher explaining the purpose of the research, providing you with an information sheet, giving you opportunity to ask questions, and then if you wish to participate, asking you to sign a consent form. **You will then be asked to complete a questionnaire about using the Resource Kit. This questionnaire will take about 10 minutes to complete. You will complete this assessment in person, not virtually.**

8. What are the possible disadvantages and risks of taking part?

If you choose to take part, you will be contributing to a National Institute for Health Research (NIHR) study. The AQUEDUCT research team considers there to be minimal disadvantages to participating in this study.

9. What are the possible benefits of taking part?

There will be no immediate benefits to you for taking part in this study; however, you may be introduced to some new ideas about best practice for crisis teams who manage dementia. The AQUEDUCT research team cannot promise that the study will help you directly, but the information obtained from this study may help to improve the work of crisis teams in the future.

10. What if something goes wrong?

If you have a concern about any aspect of this study, you should ask to speak to one of the researchers who will do their best to answer your questions. The AQUEDUCT research team's contact details are given at the end of this information sheet.

If you would like to speak to someone about any other issues raised for you during the course of the study, or to make a complaint, please contact:

_____

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11. How will we use information about you?

We will need to use information from you for this research project. This information will include:

- your name
- your contact details

People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We

will keep all information about you safe and secure. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

12. What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

13. Where can you find out more about how your information is used?

You can find out more about how we use your information:

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from www.hra.nhs.uk/information-about-patients/research
- by asking one of the research team
- by sending an email to DPOEnquiries@nottshc.nhs.uk
- or by ringing us on 0115 7484323 (AQUEDUCT administrator's number).

14. What will happen to the results of the research study?

Results from this study will inform use of the Resource Kit by teams working with people with dementia and their carers in crises, and if successful, it will support other teams nationwide. If you would like to know the results, please tell the AQUEDUCT research team and they will send you a summary. Great care will be taken to ensure that no identifiable participant information will be used in the results and all such information will be kept as strictly confidential.

15. Who is organising and funding the research?

The research is funded by the Department of Health and Social Care's National Institute for Health Research. The research study is led by Professor Martin Orrell, who is Director of the Institute of Mental Health, Nottingham.

16. Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee. Research Ethics Committees safeguard the rights, safety, dignity and well-being of people participating in research in the National Health Service. They review applications for research and give an opinion about the proposed participant involvement and whether the research is ethical. This study has been reviewed by such a Research Ethics Committee.

17. Contact for further information

Local site Principal Investigator:

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OR

Dr Donna Maria Coleston
(Consultant Clinical Psychologist)
AQUEDUCT Project Manager
AQUEDUCT Research Team
Institute of Mental Health
Nottingham NG7 2TU
0115 7484323 (AQUEDUCT administrator's number)

Appendix 8: for WP3.2

Consent Form 3 – for TMCD Practitioners Version 3 01.03.2021

PARTICIPANT IDENTIFICATION CODE:

CONSENT FORM

Title of Study: **Achieving Quality and Effectiveness in Dementia Using Crisis Teams (AQUEDUCT) Main Trial**

Name of Chief Investigator: **Professor Martin Orrell**

Please initial all boxes

1. I confirm that I have read and that I understand information sheet D (version 3, dated 01.03.2021) for the above study. I have had opportunity to consider the information and to ask questions, and these questions have been answered satisfactorily. ☐

2. I understand that my participation is entirely voluntary and that I am free to withdraw at any time without giving any reason, without my legal rights being affected. ☐

3. I understand that sections of data collected during the study that are relevant to my participation may be looked at by individuals from regulatory authorities or from the NHS Trust sponsor. I give permission for these individuals to have access to these data. ☐

4. I understand that if I disclose something that indicates risk of harm to me or to others, the AQUEDUCT research team is obligated to inform the appropriate authorities. ☐

5. I agree to take part in the above study. ☐

_____	_____	_____
Name of participant	Date	Signature
_____	_____	_____
Name of person taking consent	Date	Signature

One copy for participant and one copy for investigator file

AQUEDUCT Study

AQUEDUCT stands for Achieving Quality and Effectiveness in Dementia Using Crisis Teams. We would like to invite you to take part in this research study.

What is the purpose of the study?

This study is about an online Resource Kit we have developed. The findings from this study will show us how useful the Resource Kit is when it is used by clinical teams who work with people with dementia who are experiencing a crisis.

Why have I been invited to take part?

We would like to talk to you because you have recently used a team that works with people who have dementia and who have experienced a crisis.

We would like to talk to you about your experience of receiving care from this team. This information will help us to evaluate the Resource Kit that will support teams like the one you used and help them to provide the best care possible.

Do I have to take part?

It is up to you to decide whether or not to take part. Taking part in this study is entirely voluntary. If you decide to take part, you will be given this information sheet to keep and you will be asked to sign a consent form. You will still be free to withdraw at any time without giving a reason. The care you receive from the clinical team will not change if you do not take part in the study or if you withdraw from the study.

What will I have to do?

We will ask you some questions, and this will take about 30 minutes. Everything you tell us will be kept as confidential. **You will complete this interview virtually, not in person, by telephone or by multi-media.**

If possible, the interview will be recorded so that an anonymous written copy can be made of what is said, to help the AQUEDUCT research team to analyse the interview. **The interview can take place on the telephone or using multi-media if you have a laptop or tablet, whichever suits you best.** The recording will be made by the AQUEDUCT researcher, not through the phone or laptop. A special coded version of the recording will then be sent so that it can be typed

up – this coding will protect your identity. The recording will be deleted when the written copy is made.

If we ask you a question that you do not want to answer, please do not worry. Deciding not to answer any questions will not have any impact on how you are treated by the team.

What are the possible risks or benefits of taking part?

We do not think there will be any risks involved in taking part in this study. There will be no immediate benefits to you for taking part; however, you may be introduced to some new ideas about good practice for crisis teams who work with people with dementia. The AQUEDUCT research team cannot promise that the study will help you directly, but the information we get may help to improve the work of crisis teams in the future.

What if something goes wrong?

We are not expecting anyone to become upset while answering these questions, but if you would like to talk to someone about any issues raised, or to make a complaint, please contact your local Patient Advice and Liaison Service (PALS). Here are their contact details:

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How will we use information about you?

In this research study we will use information from you – we will use your name and your contact details. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study.

Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules.

At the end of the study we will save some of the data in case we need to check it. We will make sure no-one can work out who you are from the reports we write.

Please feel free to discuss this study with your family and friends before deciding whether to take part and if you have any questions, please ask us.

You can contact EITHER the local site Principal Investigator

_____

_____

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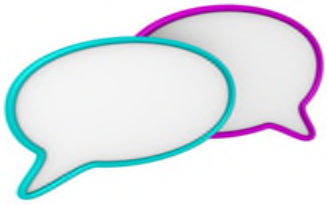
_____

OR

Dr Donna Maria Coleston
(Consultant Clinical Psychologist)
AQUEDUCT Project Manager
AQUEDUCT Research Team
Institute of Mental Health
Nottingham NG7 2TU
0115 7484323 (AQUEDUCT administrator's number)



Appendix 10: for WP3.2

Participant Information Sheet F – for People with Dementia and Carers

Version 3 01.03.2021

1. **Research Study Title – Achieving Quality and Effectiveness in Dementia Using Crisis Teams (AQUEDUCT): A Randomised Controlled Trial of a Resource Kit for Teams Managing Crisis in Dementia**

2. **Name of Chief Investigator – Professor Martin Orrell**

3. **Invitation**

You are being invited to take part in a research study. Before you decide whether you would like to participate in the 'Achieving Quality and Effectiveness in Dementia Using Crisis Teams' (AQUEDUCT) study, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully, and ask us about anything that is unclear or if you require any further information. Please take time to decide whether or not you wish to participate in the study. Thank you for your time.

4. **What is the purpose of the study?**

The purpose of this AQUEDUCT study is to investigate the use of a Resource Kit in practice with Teams Managing Crisis in Dementia (TMCDs). The Resource Kit is for use by teams with people with dementia and their carers at times of crisis. This study looks at use of the Resource Kit in practice and related costs. The findings and your feedback from this study will help us to evaluate how useful the Resource Kit has been.

5. **Why have I been invited to participate?**

You have been invited to participate because you have received input from a Team Managing Crisis in Dementia in the past six months. This team was involved in our research. We would now like to ask for your feedback on the input you received from the Team Managing Crisis in Dementia during the study period. This feedback is gathered at the end of the team's involvement in the research.

6. **Do I have to take part?**

It is up to you to decide whether or not to take part. Taking part in this research is entirely voluntary. If you do decide to take part, you will be given this information sheet to keep and you will be asked to sign a consent form. You will still be free to withdraw at any time without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not adversely affect your input from the clinical team. If at any point you wish to withdraw from the study, you may also withdraw your data; however, during analysis stages in cases where anonymised data have been used, data withdrawal may not be possible as any identifiable information will have been removed.

7. What will happen to me if I agree to take part?

This part of the AQUEDUCT study will firstly involve a researcher explaining the purpose of the research, providing you with an information sheet, giving you opportunity to ask questions, and then if you wish to participate, asking you to sign a consent form. **You will then be asked to take part in a brief interview about the input you received from the Team Managing Crisis in Dementia during their involvement in the AQUEDUCT study. This interview will take about 30 minutes to complete, and it will involve you speaking (perhaps on the telephone or using multi-media if you have a laptop or tablet) to the AQUEDUCT researcher as you answer their questions. You will thus, complete this interview virtually, not in person.** Any cost incurred, such as the cost of a telephone call, will be met by the AQUEDUCT research programme.

If possible, the interview will be recorded so that an anonymous written copy (a transcription) can be made of what is said, to help the AQUEDUCT research team to analyse the interview. Although interviews will take place remotely by phone or by multimedia means, the audio recording will be made on a digital voice recorder by the AQUEDUCT researcher. Audio recordings will not be made *via* the phone or laptop. Recordings will be encrypted, and encrypted material only will be sent for transcription. The recording will be deleted when the transcription has been finished.

8. What are the possible disadvantages and risks of taking part?

If you choose to take part, you will be contributing to a National Institute for Health Research (NIHR) study. The AQUEDUCT research team considers there to be minimal disadvantages to participating in this study.

9. What are the possible benefits of taking part?

There will be no immediate benefits to you for taking part in this study; however, you may be introduced to some new ideas about best practice for crisis teams who manage dementia. The AQUEDUCT research team cannot promise that the study will help you directly, but the information obtained from this study may help to improve the work of crisis teams in the future.

10. What if something goes wrong?

If you have a concern about any aspect of this study, you should ask to speak to one of the researchers who will do their best to answer your questions. The AQUEDUCT research team's contact details are given at the end of this information sheet.

If you would like to speak to someone about any other issues raised for you during the course of the study, or to make a complaint, please contact:

_____

_____

_____

_____

11. How will we use information about you?

We will need to use information from you for this research project. This information will include:

- your name
- your contact details

People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

12. What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

13. Where can you find out more about how your information is used?

You can find out more about how we use your information:

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from www.hra.nhs.uk/information-about-patients/research
- by asking one of the research team
- by sending an email to DPOEnquiries@nottshc.nhs.uk
- or by ringing us on 0115 7484323 (AQUEDUCT administrator's number).

14. What will happen to the results of the research study?

Results from this study will inform use of the Resource Kit by teams working with people with dementia and their carers in crises, and if successful, it will support other teams nationwide. If you would like to know the results, please tell the AQUEDUCT research team and they will send you a summary. Great care will be taken to ensure that no identifiable participant information will be used in the results and all such information will be kept as strictly confidential.

15. Who is organising and funding the research?

The research is funded by the Department of Health and Social Care's National Institute for Health Research. The research study is led by Professor Martin Orrell, who is Director of the Institute of Mental Health, Nottingham.

16. Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee. Research Ethics Committees safeguard the rights, safety, dignity and well-being of people participating in research in the National Health Service. They review applications for research and give an opinion about the proposed participant involvement and whether the research is ethical. This study has been reviewed by such a Research Ethics Committee.

17. Contact for further information

Local site Principal Investigator:

_____

_____

_____

_____

OR

Dr Donna Maria Coleston
(Consultant Clinical Psychologist)
AQUEDUCT Project Manager
AQUEDUCT Research Team
Institute of Mental Health
Nottingham NG7 2TU
0115 7484323 (AQUEDUCT administrator's number)

Appendix 11: for WP3.2

Consent Form 4 – for People with Dementia and Carers Version 3 01.03.2021

PARTICIPANT IDENTIFICATION CODE:

CONSENT FORM

Title of Study: **Achieving Quality and Effectiveness in Dementia Using Crisis Teams (AQUEDUCT) Main Trial**

Name of Chief Investigator: **Professor Martin Orrell**

Please initial all boxes

1. I confirm that I have read and that I understand information sheet E or F (version 3, dated 01.03.2021) for the above study. I have had opportunity to consider the information and to ask questions, and these questions have been answered satisfactorily. ☐
2. I understand that my participation is entirely voluntary and that I am free to withdraw at any time without giving any reason, without my legal rights being affected. ☐
3. I understand that sections of data collected during the study that are relevant to my participation may be looked at by individuals from regulatory authorities or from the NHS Trust sponsor. I give permission for these individuals to have access to these data. ☐
4. I understand that the interview will be recorded and that this recording will be processed, stored and used as outlined in information sheet E or F (version 3, dated 01.03.2021). ☐
5. I understand that if I disclose something that indicates risk of harm to me or to others, the AQUEDUCT research team is obligated to inform the appropriate authorities. ☐
6. I agree to take part in the above study. ☐

Name of participant	Date	Signature
Name of person taking consent	Date	Signature

One copy for participant and one copy for investigator file

Appendix 12: AQUEDUCT WP3 (Main Trial) Case Report Form Index

AQUEDUCT Case Report Form (CRF) Index for Each Participating TMCD

- **TMCD Initial Screening Form – to include details of COVID-19 restrictions in local area**
- **Post-training Self-administered Assessment on the RK (for intervention arm only)**

- **WP3.1 – Randomised Controlled Trial of the RK**
  - Whole site register of participants (ID codes only)
  - For each participant:
    - Informed consent (who took consent, when)
    - Eligibility checklist (different for each participant type)
      - TMCD practitioners (employed in a Team Managing Crisis in Dementia)
      - People with dementia (diagnosis of dementia, accessed TMCD during RCT)
      - Carers (carer for person with dementia, accessed TMCD during RCT)
    - Demographic details (different for each participant type)
      - TMCD practitioners (age, gender, ethnicity, job title and banding, whole time equivalence specifically in TMCD plus in NHS overall)
      - People with dementia (age, gender, ethnicity, diagnosis, time since diagnosis)
      - Carers (age, gender, ethnicity, relationship to person with dementia)

- **WP3.2 – Qualitative Evaluation of the Experience of Using, or Receiving Input from a TMCD Using, the RK**
  - Whole site register of participants (ID codes only)
  - For each participant:
    - Informed consent (who took consent, when)
    - Eligibility checklist (different for each participant type)
      - TMCD practitioners (employed in a Team Managing Crisis in Dementia during RCT)
      - People with dementia (diagnosis of dementia, accessed TMCD during RCT)
      - Carers (carer for person with dementia, accessed TMCD during RCT)
    - Demographic details (different for each participant type)
      - TMCD practitioners (age, gender, ethnicity, job title and banding, whole time equivalence specifically in TMCD plus in NHS overall)
      - People with dementia (age, gender, ethnicity, diagnosis, time since diagnosis, time since TMCD input ended)
      - Carers (age, gender, ethnicity, relationship to person with dementia, time since TMCD input ended)