

# Enhancing medicines organisation with people with dementia and family carers

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<b>Registration date</b> 12/05/2023	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 16/04/2025	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Many people with dementia live with other health conditions requiring them to take multiple medications. The confusion associated with dementia may make it difficult for people to manage medicines. Problems include taking incorrect doses of medicines, difficulties accessing medicines and lack of communication with professionals. Past approaches have focused on ensuring people take their medicines on time, however, active involvement can help with a broader range of problems. This project aims to develop and test a personalised support programme to improve medicines management for people with early dementia living at home and their family carers. The programme will promote active patient and carer involvement, enhancing knowledge and skills in medicine management. Patients and family carers will benefit through shaping the research, and should the intervention be successful, there is potential to improve their quality of life and health.

### Who can participate?

People with mild-moderate dementia living at home taking two or more medicines. Family or friends involved in supporting the person with dementia participating in the study. Health and social care professionals involved in organising medicines for people with mild-moderate dementia.

### What does the study involve?

Step 1: Identify how people living with dementia and family carers manage medicines.

Interviews, photos, written accounts and conversations with people with early dementia and family carers will be collected. Interviews will be with health and social care professionals.

Themes identified from interviews will help us learn what strategies people with dementia and family apply, and how professionals support these strategies.

Step 2: Co-designing a support programme with people living with dementia, family carers and health care professionals. We will hold a series of workshops to develop the intervention, asking the participants to discuss the step 1 evidence and identify methods of support for medicines management.

Step 3: A test to ensure the support programme is acceptable and feasible. We will recruit people living with dementia and family carers to try the intervention and interview them about their experiences.

The PPI group will help us throughout the research programme – as advisors, to steer the project and with practical tasks, such as being co-researchers finding themes in interviews. Regular meetings will be held.

The research will be disseminated through academic papers, conferences, social media, and contacting organisations relevant to medicines management. The PPI group will inform and take an active role in the dissemination strategy.

What are the possible benefits and risks of participating?

Those who take part will be helping to potentially support people with dementia and family /friends with medicines management in the future. They may enjoy speaking to the research team about their experiences. People taking part may become tired when answering the questions.

Where is the study run from?

Bradford Teaching Hospitals Foundation Trust, and involves the University of Bradford, University of Leeds, Affinity Care, and Meri Yaadain.

When is the study starting and how long is it expected to run for?

July 2021 to March 2026

Who is funding the study?

National Institute for Health and Social Care Research (NIHR) Research for Patient Benefit (RfPB)

Who is the main contact?

Dr Catherine Powell, c.powell2@bradford.ac.uk

### **Study website**

<https://psrc-yh.nihr.ac.uk/the-magnet-study/>

## **Contact information**

### **Type(s)**

Principal Investigator

### **Contact name**

Dr Catherine Powell

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# Additional identifiers

## EudraCT/CTIS number

Nil known

## IRAS number

320482

## ClinicalTrials.gov number

Nil known

## Secondary identifying numbers

CPMS 55604, IRAS 320482

# Study information

## Scientific Title

Enhancing Medicines self-mAnaGemeNt in community-dwelling people living with dEmenTia and family carers - The MAGNET Study

## Acronym

MAGNET

## Study objectives

How can community-dwelling people with mild-moderate dementia with and without family carers be supported to safely self-manage medicines?

Key aims:

1. To explore and improve how people with mild-moderate dementia with and without their family self-manage medicines using the theory of resilience in healthcare
2. Co-design an intervention for people living with mild-moderate dementia with and without their family carers to safely self-manage their medicines
3. Assess the feasibility of the co-designed community-based psychosocial intervention.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approved 13/03/2023, London - Brent Research Ethics Committee (London Road, Skipton House, SE1 6LH, London, UK; +44 (0)207 1048084; brent.rec@hra.nhs.uk), ref: 23/PR/0180

## Study design

Mixed-methods non-randomised study

## Primary study design

Interventional

## Secondary study design

Non randomised study

**Study setting(s)**

Community, Other

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

**Health condition(s) or problem(s) studied**

Dementias and neurodegeneration

**Interventions**

This research will build on the existing evidence base to co-design a community-delivered psychosocial intervention for medicines self-management strategies at home applying Experienced Based Co-design (EBCD), a participatory approach involving partnership between patients and professionals to improve services. The project will follow key phases reflecting current Medical Research Council (MRC) guidance on the development, testing and evaluation of interventions.

The research will be based in three diverse healthcare areas in Yorkshire, with differing levels of deprivation, urban and rural populations will be included. We will recruit health and social care professionals, people with mild-moderate dementia and family carers through community-based organisations including GP practices, memory clinics, and third-sector organisations in these areas.

We will use a mixed-methods approach, underpinned by resilience in healthcare theory. Phase one will involve qualitative interviews, verbal or written accounts, photos, and healthcare resource data, with 24 people with mild-moderate dementia with and without family carers; and 18 health/social care professional's interviews.

We will learn from patients how they are able to respond, anticipate, learn and monitor their medicines self-management strategies, and how these strategies support them across changes they experience through time. Semi-structured interviews will be completed with 24 people living with dementia and family carers. Interviews will be retrospective and prospective. The interviews will be recorded by video (with consent) in preparation for Phase Two to inform intervention development. Self-reported experiences will be collated through weekly verbal or short written personal (diary) accounts at weeks 2, 3, 4, 5, 6, and 7. Photos will be taken by the person living with dementia and family carers in their own time to capture how medicine self-management processes may alter over time, or fluctuate at different times of the day, and help to identify key moments in the medicine self-management process.

Phase two comprises an adapted experienced-based co-design of an intervention with staff and patients. The method involves the use of a trigger film of patient experiences as a catalyst for change. Patient experiences from Phase One and an existing video on medicines self-management from a PPI group member living with dementia will be drawn upon. Expertise will be drawn from the Medicines Optimisation Research Group based at the University of Bradford. The group has a strong track record of developing healthcare interventions using EBCD. We will utilise an expert facilitator for the process as recommended in our previous research.

A maximum of 18 people living with dementia and family carers from each area will be brought together to watch the trigger film made in Phase One. Separate professional groups will be held with a maximum of 9 professionals. Following these separate events, a joint event will be held with both groups of people with dementia, family carers and professionals, with a maximum of 27 participants. The sample size is based on previous EBCDs. Outputs from our existing systematic review will be presented, alongside data analysis from Phase One and a video. The video will contain extracts from patient interviews. Following the video, participants will be asked to consider the emotional touchpoints for these patients, drawing on their own experiences, and identify a long list of priorities for change and improvement. At the joint event, participants will debate the long list and prioritise up to three key areas that will be taken forward for the next stage.

Two co-design workshops with 6 people living with dementia and family carers and 3 health and social care professionals will then be facilitated in the 3 areas (n=27) to develop the intervention, based on the priorities and perspectives highlighted from the separate and joint events. We envisage these will be face-to-face but can be facilitated online.

Ethics approval will be sought for Phase Three of the study. Phase three involves a pre-test, post-test non-randomised feasibility study to assess the feasibility of implementing a co-designed intervention, and determining procedures for the RCT. The aim is to assess the feasibility of the co-designed community-based psychosocial intervention. Our key objectives are to: i) assess the feasibility and acceptability of implementing the co-designed intervention for people living with mild-moderate dementia, family carers and community-based health and social care professionals in preparation for a randomised controlled trial ii) develop materials for estimating the healthcare resource use of participants, the costs of the intervention and the subsequent resource in both arms of a randomised controlled trial. iii) assess the feasibility of collecting a range of cost-effectiveness measures.

We will recruit 72 people, including people with mild-moderate dementia, and family carers where available. The size is based on the need to understand whether it is possible to consistently recruit 4 participants a week for 6 weeks per site.

Qualitative and quantitative data will be collated as outlined above for 72 participants across 3 sites. Data will be collated at preintervention (baseline), during the intervention end of months 1 and 2 (questionnaires) post-intervention (follow up at month 3) (interviews and questionnaires). Observations will be conducted with a maximum of 72 participants at the end of month 2. Interviews will be conducted with 20 people with dementia and family carers and 3 facilitators. We will assess recruitment strategy, capability and sample characteristics, data collection procedures and outcome measures, intervention acceptability, study procedures, and preliminary responses to the intervention. We will determine the main outcome measure for a future RCT. Criteria to determine if the intervention could proceed to an RCT will be based on study recruitment, intervention delivery, and participant attendance. Following a feasibility study, we will identify strategies to address challenges and finalise the intervention and implementation guidelines. If the results support feasibility, findings will be used to inform the development and implementation of a future RCT.

## **Intervention Type**

Other

## **Phase**

Not Specified

## **Primary outcome measure**

Phase One: Explore how people with mild-moderate dementia self-manage medicines using the theory of resilience in healthcare

1. Learn from patients and family carers how they can respond, anticipate, learn and monitor medicines self-management strategies, how these strategies support them across changes they experience through time, and health resource use measured using qualitative interviews, verbal or written accounts, diaries, photos, and analysed using framework analysis during Phase One.
2. Learn which health and social care professionals are involved, and how they can support people with dementia and family members to respond, anticipate, learn and monitor their medicines self-management strategies measured through interviews during Phase One.

## **Secondary outcome measures**

Phase Two: Intervention development will be informed by the output from Phase One and joint events.

3. Up to three key areas will be taken forward for the next stage of a co-designed intervention with staff and people with dementia measured using various methods including a trigger film of patient experiences as a catalyst for change, patient experiences from Phase One, an existing video on medicines self-management from a PPI group member living with dementia and expertise of the study team, and co-design workshops during Phase Two (months 7-15).

Phase Three: Outcome measures assessed in Phase Three will be determined from Phases One and Two.

## **Overall study start date**

31/07/2021

## **Completion date**

29/03/2026

# **Eligibility**

## **Key inclusion criteria**

Participants will be people with dementia, family carers, and health and social care professionals. People with dementia will be:

1. Living with mild-moderate dementia (as indicated by a Mini-Mental State Examination) score between 24 and 10).
2. Using two or more medicines
3. Living at home
4. Living alone or living with family carers

Family carers will be:

1. Relatives, friends or neighbours identified as involved in supporting the person with their medicines
2. Caring for a person with mild-moderate dementia (as indicated by a Mini-Mental State Examination) score between 24 and 10), using two or more medicines, and living at home
3. Maybe living within or outside the household of the person with dementia

Health and social care professionals will be:

Community health and social care professionals who are supporting a person with dementia and family carers with medicines in the home environment.

**Participant type(s)**

Healthy volunteer, Patient, Health professional

**Age group**

Adult

**Sex**

Both

**Target number of participants**

Planned Sample Size: 117; UK Sample Size: 117

**Key exclusion criteria**

People with dementia will be excluded if they are any of the following:

1. Using fewer than two medicines
2. Living in care homes
3. Live with moderate to advanced dementia
4. Lack capacity to consent
5. On the End-of-Life Pathway
6. Unable to communicate verbally

Family carers will be excluded if they are either of the following:

1. Not a relative, friend or neighbour identified as involved in care for the person
2. The person they are caring for has advanced dementia, using fewer than two medicines, and /or not living at home

Health and social care professionals will be excluded if they are any of the following:

1. Have involvement with a person recruited as part of this study (i.e. is a patient of theirs)
2. Not based within the community
3. The people they support have advanced dementia, not living at home
4. Have no involvement with patients with mild-moderate dementia, on two or more meds

**Date of first enrolment**

17/05/2023

**Date of final enrolment**

30/06/2025

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Bradford Teaching Hospitals NHS Foundation Trust**

Bradford Royal Infirmary

Duckworth Lane

Bradford  
United Kingdom  
BD9 6RJ

## Sponsor information

### Organisation

Bradford Teaching Hospitals NHS Foundation Trust

### Sponsor details

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### Sponsor type

Hospital/treatment centre

### Website

<https://www.bradfordhospitals.nhs.uk/>

### ROR

<https://ror.org/05gekvn04>

## Funder(s)

### Funder type

Government

### Funder Name

Research for Patient Benefit Programme

### Alternative Name(s)

NIHR Research for Patient Benefit Programme, RfPB

### Funding Body Type

Government organisation

### Funding Body Subtype

National government

**Location**

United Kingdom

## **Results and Publications**

**Publication and dissemination plan**

Planned publication in a high-impact peer reviewed journal

**Intention to publish date**

31/03/2025

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are not expected to be made available due to confidentiality reasons.

**IPD sharing plan summary**

Not expected to be made available