Using automatic medication dispensers to improve medication adherence for older adults with long-term conditions

Submission date	Recruitment status Recruiting	[X] Prospectively registered		
14/03/2025		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
31/03/2025	Ongoing Condition category	☐ Results		
Last Edited		☐ Individual participant data		
03/11/2025	Other	[X] Record updated in last year		

Plain English summary of protocol

Background and study aims

This study aims to evaluate the effectiveness of a new automated medication dispensing device designed for people with long-term health conditions. The device provides reminders for taking medication and sends alerts to family members or carers if doses are missed. The goal is to determine whether the device can improve medication adherence and support overall health and wellbeing.

Who can participate?

Adults with long-term health conditions who take regular medication and sometimes struggle to manage their medication routine may be eligible to participate.

What does the study involve?

Participants will be randomly assigned to one of two groups:

A group using the automated medication dispensing device for six months.

A group continuing with their usual medication routine.

Participants may be asked to provide feedback through surveys or interviews to help researchers understand how the device fits into daily life.

What are the possible benefits and risks of participating?

Benefits:

Participants in the device group may find it easier to manage their medication.

The study contributes to research that could benefit others with similar conditions.

Risks:

There are no significant risks expected. Participants may need time to adjust to using the device.

Where Is the study run from? University of Bedfordshire (UK)

When Does the Study Start and For How Long? September 2024 to August 2026

Who is funding the study?
Bedford, Luton and Milton Keynes (BLMK) Integrated Care Research and Innovation Hub (UK)
NHS England

Who Is the Main Contact? For further information or to express interest, individuals can contact: Dr Jodi Emma Wainwright, jodiemma.wainwright@beds.ac.uk

Contact information

Type(s)

Scientific, Principal investigator

Contact name

Dr Erica Cook

ORCID ID

https://orcid.org/0000-0003-4369-8202

Contact details

University of Bedfordshire, University Square Luton United Kingdom LU1 3JU +44 1582 489217 erica.cook@beds.ac.uk

Type(s)

Public

Contact name

Dr Jodi Emma Wainwright

ORCID ID

https://orcid.org/0000-0002-6297-499X

Contact details

University of Bedfordshire, Putteridge Bury Luton United Kingdom LU2 8LE +44 7566729241 jodiemma.wainwright@beds.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

IHREC1039

Study information

Scientific Title

Assessing the impact of Automated Devices for enhancing HEalth and Reducing medication Errors in older Adults with long-term health conditions: A Randomised Controlled Trial

Acronym

ADHERE

Study objectives

Current study objectives as of 03/11/2025:

Are Automated Medication Devices (AMDs) for adults aged over 50 with long term health conditions, more effective than standard care in improving medication adherence, quality of life, and health status after six months? Which groups does it work best for, and why?

Previous study objectives:

Are Automated Medication Devices (AMDs) for adults aged over 65 with long term health conditions, more effective than standard care in improving medication adherence, quality of life, and health status after six months? Which groups does it work best for, and why?

Ethics approval required

Ethics approval required

Ethics approval(s)

1. approved 13/03/2025, East of England - Essex Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8106; essex.rec@hra.nhs.uk), ref: 25/EE/0026

2. approved 26/11/2024, Institutue for Health Research Ethics Committee (University of Bedfordshire, University Square,, Luton, LU1 3JU, United Kingdom; +44 1234 400 400; EthicsIHR@beds.ac.uk), ref: IHREC1039

Study design

Multicentre interventional randomized controlled trial

Primary study design

Interventional

Study type(s)

Efficacy, Quality of life

Health condition(s) or problem(s) studied

Adults aged over 50 with long term health conditions

Interventions

Current interventions as of 03/11/2025:

There are two study arms, intervention and control. Each group will complete assessments at baseline, 3 and 6 months. The intervention group will receive the AMD and the control group will continue to take medication as normal.

We will be sequentially allocating participants to trials arms taking in to account the covariates of interest. In this case, gender (Male vs Female), age (50-65 vs 65-75 vs 75+), and the referral reason for entering the trial (Physical vs memory related) will be used to ensure that trial arms are balanced for these factors. Specially designed software will be used to manage this process called MinimPy2.

Previous interventions:

There are two study arms, intervention and control. Each group will complete assessments at baseline, 3 and 6 months. The intervention group will receive the AMD and the control group will continue to take medication as normal.

We will be sequentially allocating participants to trials arms taking in to account the covariates of interest. In this case, gender (Male vs Female), age (65-75 vs 75+), and the referral reason for entering the trial (Physical vs memory related) will be used to ensure that trial arms are balanced for these factors. Specially designed software will be used to manage this process called MinimPy2

Intervention Type

Device

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Pivotell Advance Automatic Pill Dispenser (Patent No. SE 535 462 C2)

Primary outcome(s)

- 1. Medication Refill Adherence (MRA) at baseline, 3 and 6 months
- 2. Self-report adherence data at baseline, 3 and 6 months
- 3. Adherence data for the intervention group will also be determined by using the Pivotell Administration Centre at 3 and 6 months

Key secondary outcome(s))

- 1. Quality of Life 12-item Short-Form Health Survey (SF-12) at baseline, 3 and 6 months
- 2. Morisky Medication Adherence Scale (MMAS-8) at baseline, 3 and 6 months
- 3. Self-report healthcare resource use data at baseline. 3 and 6 months

Completion date

31/08/2026

Eligibility

Key inclusion criteria

Current inclusion criteria as of 03/11/2025:

- 1. Adults (≥50 years)
- 2. Diagnosed with at least one long-term health condition
- 3. Prescribed a stable daily medication regime and not taking medication more than four times per day
- 4. Has physical and/or memory-related difficulties taking medication and/or self-reported low medication adherence
- 5. And /or unsuccessfully tried other compliance aids, such as dosette boxes, calendar clocks, blister packs or talking labels.
- 6. Have sufficient English language skills
- 7. The patient provides written informed consent

Previous inclusion criteria:

- 1. Adults (≥65 years)
- 2. Diagnosed with at least one long-term health condition
- 3. Prescribed a stable daily medication regime and not taking medication more than four times per day
- 4. Has physical and/or memory-related difficulties taking medication and/or self-reported low medication adherence
- 5. And /or unsuccessfully tried other compliance aids, such as dosette boxes, calendar clocks, blister packs or talking labels.
- 6. Have sufficient English language skills
- 7. The patient provides written informed consent

Participant type(s)

Patient, Service user

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

50 years

Sex

All

Key exclusion criteria

- 1. Patients on cytotoxic medications (e.g. Methotrexate)
- 2. Clinically unsuitable medications or medications unsuitable for the AMD used (e.g., size, storage, administration method)
- 3. Variable medication regime (e.g. Warfarin) and/or taking medication more than four times per day
- 4. Patients who are already using an AMD or other similar electronic device.
- 5. Patients are not responsible for taking their own medications (e.g. carer administers medication).
- 6. The patient does not provide informed consent.

Date of first enrolment

01/04/2025

Date of final enrolment 28/02/2026

Locations

Countries of recruitment

United Kingdom

England

Study participating centre The Village Pharmacy

Meiklejohn Centre Unit 3 Kingswood Way Great Denham Bedford United Kingdom MK40 4GH

Study participating centre Makan's Pharmacy

453 Dunstable Road Luton United Kingdom LU4 8DE

Study participating centre Moakes Pharmacy

Unit 3
Marsh Farm Shopping Centre
The Moakes
Luton
United Kingdom
LU3 3FH

Study participating centre Hockwell Ring Pharmacy

5-7 the Green Hockwell Ring

Luton United Kingdom LU4 9PG

Study participating centre Titan Pharmacy

17-18 Bedford Square Houghton Regis Dunstable United Kingdom LU5 5ES

Study participating centre Halfway Pharmacy

731 Dunstable Road Luton United Kingdom LU4 0DU

Study participating centre Smarta Healthcare

5 Stephenson Court Priory Business Park Bedford United Kingdom MK44 3WJ

Study participating centre Lindleys Chemist

15 Ford End Road Queens Park Bedford United Kingdom MK40 4JE

Sponsor information

Organisation

University of Bedfordshire

ROR

https://ror.org/0400avk24

Funder(s)

Funder type

Other

Funder Name

NHS England

Funder Name

Bedford, Luton and Milton Keynes (BLMK) Integrated Care Research and Innovation Hub

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a publicly available repository: https://reshare.ukdataservice.ac.uk/

Anonymised data will be made available from the end of the trial for five years. This will include individual anonymised participant data and study publications including the study protocol, statistical analysis plan, health economics plan, and case report forms. Data from this study will be available via a sponsor-controlled application process for which applicants must show that they have sound scientific reasons for accessing the data and acceptable research methods. Consent for the sharing of anonymised data will be obtained from all study participants. At the culmination of the study, we plan to apply to share our anonymised data in a public repository such as the UK Data Archive https://reshare.ukdataservice.ac.uk/ where it would be accessible to other researchers. In order to enable this, we will highlight on our Participant Information Sheets and consent forms that anonymised data may be shared in this way.

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			27/03/2025	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes