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

Submission date
14/03/2025

Recruitment status
Recruiting

Registration date
31/03/2025

Overall study status
Ongoing

Last Edited
27/03/2025

Condition category
Other

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English Summary

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:
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Study website
https://www.beds.ac.uk/ihr/adhere/

Contact information

Type(s)
Scientific, Principal Investigator

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Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number
349006

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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 hypothesis
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

Secondary study design
Randomised controlled trial

Study setting(s)
Pharmacy

Study type(s)

Quality of life, Efficacy

Participant information sheet
See outputs table

Condition
Adults aged over 65 with long term health conditions

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

Pharmaceutical study type(s)
Adherence to medication

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Pivotell Advance Automatic Pill Dispenser (Patent No. SE 535 462 C2)

Primary outcome measure
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

Secondary outcome measures
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

Overall study start date
01/09/2024

Overall study end date
31/08/2026

Eligibility

Participant 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

Age group
Mixed

Lower age limit
65 Years

Sex
Both

Target number of participants
144

Participant 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.

Recruitment start date
01/03/2025

Recruitment end date
28/02/2026

Locations

Countries of recruitment
England

United Kingdom

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
Blenheim Pharmacy
9a Blenheim Crescent
Luton
United Kingdom
LU3 1HA

Study participating centre
The Highlands Pharmacy Ltd
The Highlands
Flitwick
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Sponsor type
University/education

Website
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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

Publication and dissemination plan
A dissemination planfor the ADHERE Trial will ensure that the findings are shared effectively with all relevant stakeholders, including healthcare professionals, researchers, patients, and the broader public. The dissemination plan will prioritise the timely release of results through peer-reviewed publications, conference presentations, and patient-oriented reports, adhering to ethical standards for transparency and accuracy. Data-sharing protocols will be established to promote secondary analyses while ensuring patient confidentiality. Engaging with patient advocacy groups and using accessible formats, such as lay summaries and digital media, will facilitate a more comprehensive understanding and application of the findings in clinical practice.

Intention to publish date
31/08/2027

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