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Testing new support for people with multiple long-term health conditions

Submission date
11/09/2026

Recruitment status
Recruiting

Registration date
12/10/2026

Overall study status
Ongoing

Last Edited
29/10/2026

Condition category
Other

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

Plain English summary of protocol

Background and study aims
The prevalence of multiple long-term conditions/multimorbidity (MLTC-M) is rising. Current care primarily focuses on individual conditions, acute symptoms, and medication reviews ,neglecting broader needs like mobility, functioning, social isolation, mental health, and wellbeing, leading to fragmentation of care. Access to joined up health, social care and voluntary support services is limited. This results in a high incidence of unplanned hospital admissions, lack of personalised attention and higher costs. This trial will compare the CO-ACTION intervention to usual care. Around 300 participants (plus additional informal carers) will help assess the CO-ACTION intervention looking at wellbeing, quality of life and unplanned hospitalisations alongside a cost-effectiveness evaluation.

Who can participate?
Adults with 2 or more long-term conditions, indication of biopsychosocial need or no engagement with healthcare services in the last 12 months with self-reported need for an intervention.

What does the study involve?
Participants will have a screening call with a researcher and if eligible a baseline data collection visit (including consent and randomisation to determine which study group a participant will take part in). There will be follow-up data collection visits after 3-months, 6-month and 12-months. Participants in the intervention group will have at least three sessions with the CO-ACTION facilitator where needs will be prioritised and a support plan created and agreed. Informal carers may be recruited alongside participant with multiple long-term conditions.

What are the possible benefits and risks of participating?
Benefits: Contributing to the development of new knowledge and understanding, which could help improve MLTC-M management in the future.
Risks: No considerable risks have been identified.

Where is the study run from?
Peninsula Clinical Trials Unit (PenCTU), University of Plymouth, UK.

When is the study starting and how long is it expected to run for?
October 2026 to September 2028.

Who is funding the study?
National Institute for Health and Care Research (NIHR), UK.

Who is the main contact?
Katherine Beaney, coaction.penctu@plymouth.ac.uk.

Contact information

Type(s)
Principal investigator, Scientific, Public

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Additional identifiers

Integrated Research Application System (IRAS)
331510

Central Portfolio Management System (CPMS)
57407

National Institute for Health and Care Research (NIHR)
206260

Study information

Scientific Title
CO-ACTION: Personalised social and self-management support for better living with multiple long-term conditions in the community

Acronym
CO-ACTION

Study objectives

Primary
To compare the mental wellbeing of adults with MLTC-M receiving the CO-ACTION intervention with those receiving usual care at 6-months post-randomisation

Secondary:
To compare the effect of the CO-ACTION intervention with usual care for adults with MLTC-M on:
1. Mental wellbeing at 3-months and 12-month post-randomisation
2. Health-related quality-of-life at 3-months, 6-months and 12-months post-randomisation
3. Anxiety at 6-months and 12-months post-randomisation
4. Depression at 6-months and 12-months post-randomisation
5. Social isolation at 6-months and 12-months post-randomisation
6. Burden specific to MLTC-M management at 6-month and 12-months post-randomisation
7. Personalisation and coordination of care at 6-month and 12-months post-randomisation
8. Satisfaction with care at 6-month and 12-months post-randomisation
9. Health and social care resource use at 6-month and 12-months post-randomisation
10. Unplanned hospitalisations at 6-month and 12-month post-randomisation

Tertiary
To compare the effect of the CO-ACTION intervention with usual care for informal carers of adults with MLTC-M on:
1. Mental wellbeing at 6-months and 12-months post-randomisation
2. Health-related quality of life at 6-months and 12-month post-randomisation
3. Carer strain at 6-months and 12-months post-randomisation
4. Carer burnout at 6-month and 12-months post-randomisation
5. Health and social care resource use (carers) at 6-month and 12-months post-randomisation

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 26/05/2026, North West – Liverpool Central Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 0207 104 8241; liverpoolcentral.rec@hra.nhs.uk), ref: 25/NW/0319

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose

Treatment

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Persons encountering health services for specific procedures and health care

Interventions
CO-ACTION was co-developed to address fragmented care, unmet biopsychosocial need, treatment burden, and poor care coordination experienced by people living with MLTC. The intervention is underpinned by personalised care, shared decision making (SDM), supported self-management, integrated care coordination, motivational interviewing, and a biopsychosocial approach.
The intervention comprises:
(1) an initial biopsychosocial consultation;
(2) identification and prioritisation of unmet need;
(3) collaborative shared decision making to agree priorities and actions;
(4) development of a personalised multi-sector management plan;
(5) care coordination and facilitated access to services and resources;
(6) planned follow-up consultations;
(7) ad hoc participant-, carer-, or facilitator-initiated contact in response to changing need.

Intervention activities may include supported self-management, signposting to digital and community resources, facilitated access to peer support, referral to clinical services where urgent needs are identified, and multidisciplinary team liaison. The initial consultation is considered an intervention component.
The aims are to:
(1) improve access to biopsychosocial support;
(2) identify and prioritise unmet needs;
(3) develop personalised multi-sector management plans;
(4) support navigation across health, social care, community, and voluntary-sector services;
(5) provide ongoing coordination through a single point of contact.

It is hypothesised that addressing unmet need, improving care coordination, enhancing participant agency, and aligning services to participant priorities will improve wellbeing and reduce individual and service burden.
Participants receive an individualised management plan in accessible formats (e.g. written or recorded). Communication and intervention delivery are tailored to participant preference and accessibility needs and may include face-to-face consultations, telephone, secure email, text messaging, NHS App messaging, or other approved digital systems. The intervention combines direct participant contact with coordination activities across services and sectors and is integrated within existing local systems. Delivery may occur in primary care, community, VCSE settings, participants' homes, or remotely.

CO-ACTION is delivered by trained facilitators working within the health and care system. Facilitators develop knowledge of local services and relationships across sectors to support integrated care coordination. The intervention includes one initial consultation, at least one planned follow-up consultation, one final consultation, and unlimited ad hoc contacts as required. Consultation frequency, intensity, mode of delivery, referrals, and care planning are tailored through SDM according to participant priorities, preferences, biopsychosocial needs,

cultural context, local service availability, and access requirements. Consultations can last up to 90 minutes.

Carer involvement is optional and determined by participant preference and need. Although intervention content is individualised, fidelity is maintained through structured supervision and assessment of core intervention functions, including participant-led prioritisation, biopsychosocial review, supported self-management, motivational interviewing, collaborative care planning, safeguarding oversight, and monitoring for intervention drift.

Intervention Type
Other

Primary outcome(s)
1. Mental wellbeing measured using the Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS) at 6 months post-randomisation

Key secondary outcome(s)
1. Mental wellbeing (adults with MLTC-M) measured using the Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS at 3 months and 12 months post-randomisation

2. Health-related quality of life (adults with MLTC-M) measured using the EuroQol 5-Dimension 5-Level questionnaire (EQ-5D-5L) at 3 months, 6 months and 12 months post-randomisation

3. Anxiety (adults with MLTC-M) measured using the Hospital Anxiety and Depression Scale Anxiety subscale (HADS-A) at 6 months and 12 months post-randomisation

4. Depression (adults with MLTC-M) measured using the Hospital Anxiety and Depression Scale Depression subscale (HADS-D) at 6 months and 12 months post-randomisation

5. Social isolation (adults with MLTC-M) measured using the 3-item UCLA Loneliness Scale at 6 months and 12 months post-randomisation

6. Burden associated with management of multiple long-term conditions and mental health (adults with MLTC-M) measured using the Disease Burden Mobility Assessment (DBMA) at 6 months and 12 months post-randomisation

7. Personalisation and coordination of care (adults with MLTC-M) measured using the Person-Centred Coordinated Care Experience Questionnaire (P3CEQ) at 6 months and 12 months post-randomisation

8. Satisfaction with care (adults with MLTC-M) measured using the Measure Yourself Medical Outcome Profile (MYMOP) at 6 months and 12 months post-randomisation

9. Health and social care resource use (adults with MLTC-M) measured using a bespoke questionnaire based on the Modular Resource-Use Measure (ModRUM) at 6 months and 12 months post-randomisation

10. Unplanned hospitalisations (adults with MLTC-M) measured using a bespoke questionnaire based on the Modular Resource-Use Measure (ModRUM) at 6 months and 12 months post-randomisation

11. Tertiary outcomes (informal carers): Mental wellbeing measured using the Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS) at 6 months and 12 months post-randomisation

12. Tertiary outcomes (informal carers): Health-related quality of life measured using the EuroQol 5-Dimension 5-Level questionnaire (EQ-5D-5L) at 6 months and 12 months post-randomisation

13. Tertiary outcomes (informal carers): Carer strain measured using the Modified Caregiver Strain Index (MCSI) at 6 months and 12 months post-randomisation

14. Tertiary outcomes (informal carers): Carer burnout measured using the Carer Burnout Quiz at 6 months and 12 months post-randomisation

15. Tertiary outcomes (informal carers): Health and social care resource use among carers measured using a bespoke questionnaire based on the Modular Resource-Use Measure (ModRUM) for participating carers at 6 months and 12 months post-randomisation

Completion date
30/09/2028

Eligibility

Key inclusion criteria
1. Have a confirmed diagnosis* of two or more of high impact long-term non-communicable conditions from this list:
1.1. Arthritis or problem with back or joints
1.2. Autism or autism spectrum condition
1.3. Blindness or partial sight
1.4. Cancer in the last five years
1.5. Deafness or hearing loss
1.6. Dementia or Alzheimer’s disease
1.7. Diabetes
1.8. Frailty
1.9. Heart or Cardiovascular condition
1.10. High blood pressure
1.11. Kidney or liver disease
1.12. Learning disability
1.13. Lung or breathing condition
1.14. Mental Health condition
1.15. Neurological condition
1.16. Stroke or Transient Ischemic Attack (TIA)
2. Have EITHER a confirmed indication of biopsychosocial need OR no (healthcare) service use in the 12 months plus a self-reported need for an intervention
3. Not be currently receiving an intervention or service similar to the CO-ACTION intervention
4. Aged 18 years or over
5. Have capacity to and be willing to provide informed consent
*Self-reported for those not recruited from healthcare settings.

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
120 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
Not meeting the key inclusion criteria

Date of first enrolment
01/10/2026

Date of final enrolment
30/09/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Oaks Healthcare
26-30 London Road
Waterlooville
England
PO8 8DL

Study participating centre
Southampton Sea City Partnership
St Mary's Surgery
1 Johnson Street
Southampton
England
SO14 1LT

Study participating centre
Cross Cultural Hub
YMCA Newtown Centre
Graham Road
Southampton
England
SO14 0AW

Study participating centre
Unity 101 Community Radio
107 St. Mary's Road
Southampton
England
SO14 0AN

Study participating centre
Action Hampshire
The IncuHive Space
Hursley Park Road
Winchester
England
SO21 2JN

Study participating centre
Burmantofts, Harehills and Richmond Hill Primary Care Network
Bellbrooke Surgery, 1 Bellbrooke Avenue, Harehills
Leeds
England
LS9 6AU

Study participating centre
Improving Lives Plymouth
Ernest English House
Buckwell Street
Plymouth
England
PL1 2DA

Study participating centre

Waterside Primary Care Network, Plymouth
-
Plymouth
England
-

Study participating centre
University of Southampton
FELS, School of Health Sciences
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SO17 1BJ

Study participating centre
University of Plymouth
Faculty of Health, Express Diagnostics, 6 Research Way, Plymouth Science Park, Derriford
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PL6 8BU

Sponsor information

Organisation
University of Southampton

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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. After the trial has been reported, an pseudonymised dataset may be committed to University of Plymouth’s open access research repository: https://pearl.plymouth.ac.uk/.

• The datasets generated during and/or analysed during the current study are/will be available upon request from the CI and Sponsor (reviewed by PenCTU: penctudata@plymouth.ac.uk). After the trial has been reported, the de-identified individual participant data that underlies the results will be available on request from the Chief Investigator and the Sponsor, along with supplementary files as required (e.g., data dictionaries, analysis code, etc.). Data will be shared with (or access to the data will be provided to) requestors whose proposed use of the data has been approved by the CIs and Sponsor, under an appropriate data sharing agreement. It will not be possible to identify participants personally from any information shared. This agreement will include a term requiring that researchers do not attempt to re-identify participants. As part of consenting for the study, participants are asked to consent to the following clause 'I understand that the information collected about me may be used to support other research in the future and may be shared anonymously with other researchers'.

IPD sharing plan summary
Available on request, Stored in publicly available repository