

A link work intervention to support dental visiting in people with severe mental health difficulties: The mouth matters in mental health effectiveness and cost-effectiveness trial

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Registration date 13/03/2026	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 13/03/2026	Condition category Oral Health	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Severe mental illness affects around 1% of people. It includes depression, psychosis, and bipolar disorder. People with severe mental illness often have problems with their teeth and gums. For example, they are more likely to have missing and decayed teeth. This can affect everyday activities like eating, speaking, and smiling. It can place extra stress and burden on people living with severe mental illness.

Dentists can treat teeth and gum problems. However, people living with severe mental illness often find attending a dentist difficult. This can be for many reasons. People can feel helpless, anxious, and fearful about attending. They can find it difficult to book, plan, and get to appointments. They may also struggle to pay or arrange access to free dental care. Current dental initiatives do not help people with severe mental illness to attend the dentist.

We recently conducted a small trial where link workers helped people with severe mental illness to attend a dentist. This is called a link work intervention. Everyone taking part received their usual care, but half also received the link work intervention. We were able to recruit people to take part. We were able to follow people up over time. People liked and engaged with the intervention. The findings suggested that the link work intervention might help people to see a dentist and improve their quality of life.

We want to test the intervention on a larger scale. We want to see if it will lead to better outcomes. We also want to see how much the intervention costs. We want to do this across five NHS sites. We aim to recruit 480 people to take part.

Who can participate?

People aged 18 years and older with a severe mental health difficulty currently accessing

secondary care mental health services at the point of referral (e.g. community mental health team, early intervention for psychosis service), but who have not had a routine dental appointment in the past 3 years.

What does the study involve?

Participants will be randomly allocated to receive treatment as usual or treatment as usual plus the link work intervention. This will be decided by chance. The researchers will measure how often people in both groups visit the dentist. They will also assess their mental and oral health. They will collect this data when people come into the study and after 9 months. The team will offer interviews to patients receiving the link work intervention to understand how they found it.

What are the possible benefits and risks of participating?

The intervention aims to support people to access dental services. However, the effectiveness of the intervention is unknown, which is the reason for doing the research.

Where is the study run from?

Lancashire and South Cumbria NHS Foundation Trust (UK)

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

The research started in November 2025 and finishes in July 2029. We hope to open recruitment in May 2026.

Who is funding the study?

The National Institute for Health and Care Research (NIHR) Health and Social Care Delivery Research (HS&DR)

Who is the main contact?

Dr Jasper Palmier-Claus; j.palmier-claus@lancaster.ac.uk

Contact information

Type(s)

Principal investigator, Scientific, Public

Contact name

Dr Jasper Palmier-Claus

ORCID ID

<https://orcid.org/0000-0002-4908-2137>

Contact details

Health Innovation Campus

Lancaster University

Lancaster

United Kingdom

LA14YW

+44 (0)1524 65201

J.Palmier-Claus@lancaster.ac.uk

Additional identifiers

National Institute for Health and Care Research (NIHR)

171340

Integrated Research Application System (IRAS)

350197

Study information

Scientific Title

A link work intervention to support dental visiting in people with severe mental health difficulties: The mouth matters in mental health effectiveness and cost-effectiveness trial

Study objectives

To evaluate the effectiveness and cost-effectiveness of a link work intervention for supporting people with severe mental illness to attend a planned dental appointment. There are two main outcomes, namely: i) attendance at a routine dental appointment; and ii) oral health quality of life.

It is hypothesised that:

1. The link work intervention plus treatment as usual (TAU) will lead to greater likelihood of attendance at a planned dental appointment, compared with TAU alone.
2. The link work intervention plus TAU will lead to better oral health quality of life, compared with TAU alone.
3. The link work intervention plus TAU will be cost-effective compared with TAU alone.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 05/03/2026, East Midlands - Leicester Central Research Ethics Committee (2 Redman Place Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8118; leicestercentral.rec@hra.nhs.uk), ref: 26/EM/0030

Primary study design

Interventional

Allocation

Randomized controlled trial

Masking

Blinded (masking used)

Control

Uncontrolled

Assignment

Parallel

Purpose

Prevention, Treatment

Study type(s)

Health condition(s) or problem(s) studied

Access to planned dental care in people experiencing severe mental health difficulties.

Interventions

Treatment as usual arm: Treatment as usual will include any treatments or services that the participant would normally have access to outside of the trial. For people with severe mental illness this may include support from a care coordinator, support worker, psychologist, occupational therapist, and/or psychiatrist for care around their mental health. Treatment as usual may include medication and case management. We will monitor, rather than withhold, assessment and treatment for oral health in the treatment as usual arm.

Treatment as usual plus a link work intervention. Participants in this arm will receive treatment as usual plus the link work intervention. This will consist of six sessions with a link worker over nine-months who will offer practical and emotional support around accessing a routine dental appointment. A mental health link work intervention uses link workers to empower and assist people with severe mental illness currently supported by secondary care mental health services, but not dental services, to access planned dental appointments.

Participants will be randomly allocated to one of the two groups with 1:1 ratio, stratified by site. We will follow-up both arms after nine-months.

Intervention Type

Behavioural

Primary outcome(s)

1. Attendance at a planned dental appointment measured using data from the NHS Business Services Authority (BSA) at 9-months
2. Oral health related quality of life measured using Oral Health Impact Profile - 14 item version (OHIP-14) at 9-months

Key secondary outcome(s)

1. Self-reported attendance at a planned dental appointment (private or NHS) measured using self-report items at 9-months
2. Orofacial pain & disability measured using Manchester Orofacial Pain Disability Scale at 9-months
3. Confidence around dental visiting measured using a self-report item at 9-months
4. Self-esteem measured using the Rosenberg Self-Esteem Scale at 9-months
5. Dental anxiety measured using the Modified Dental Anxiety Scale at 9-months
6. Depression measured using the Patient Health Questionnaire at 9-months
7. General anxiety measured using the Generalised Anxiety Disorder Questionnaire (GAD-7) at 9-months

8. The number of planned dental appointments attended measured using NHS Business Services Authority (BSA) data assessed at 9-months
9. Self-reported access to free/subsidised dental care measured using self-report items at 9-months
10. Exemption status for dental care measured using the NHS Business Services Authority (BSA) at 9-months
11. Completion of a course of dental treatment measured using the NHS Business Services Authority (BSA) at 9-months
12. Self-reported utilisation of urgent or emergency dental services measured using self-report items at 9-months
13. Quality adjusted life years measured using the European Quality of Life Five-Dimensional Questionnaire (EQ-5D-5L) at 9-months
14. Utilisation of healthcare resources measured using a co-designed health economics questionnaire at 9-months

Completion date

31/07/2029

Eligibility

Key inclusion criteria

1. Aged ≥ 18 years.
2. Receipt of care from community mental health or early intervention teams at the point of referral.
3. No routine dental appointment (e.g. high street dentist, special care dentist service) in the past three years. This would include any dental examination, diagnosis, advice or treatment (e.g. fillings, root canal, extractions, crowns, dentures, bridges) resulting from a routine (non-emergency) appointment at a dental service. We do not consider emergency dental care (e.g. emergency attendance at Accident & Emergency Department or a dental hospital) within this definition, although any follow-up routine and planned appointments with a dentist would exclude the person from taking part.
4. Able to provide informed consent as determined by trained researchers in consultation with the clinical team.

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

1. Current inpatient status on psychiatric ward. This does not include people in rehabilitation homes or supported accommodation in the community.
2. Immediate risk to self or others operationalised as the presence of active intent or planning to harm oneself or others in the near future (e.g. next month). Where individuals are excluded on this basis, with the person's consent, the researcher will aim to re-contact them and/or the referrer in approximately one-months' time to determine if risk has subsided to a point where they are now eligible.
3. Enrolled in another dental randomised controlled trial.

Date of first enrolment

01/05/2026

Date of final enrolment

30/04/2028

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre**Lancashire and South Cumbria NHS Foundation Trust**

The Lantern Centre

Vicarage Lane

Fulwood

Preston

England

PR2 8DW

Study participating centre**Greater Manchester Mental Health NHS Foundation Trust**

Prestwich Hospital

Bury New Road

Prestwich

Manchester

England

M25 3BL

Study participating centre**Pennine Care NHS Foundation Trust**

225 Old Street
Ashton-under-lyne
England
OL6 7SR

Study participating centre**Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust**

St Nicholas Hospital
Jubilee Road
Gosforth
Newcastle upon Tyne
England
NE3 3XT

Study participating centre**South London and Maudsley NHS Foundation Trust**

Bethlem Royal Hospital
Monks Orchard Road
Beckenham
England
BR3 3BX

Sponsor information**Organisation**

Lancashire and South Cumbria NHS Foundation Trust

Funder(s)**Funder type****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

Only the direct research team will have access to personal data of participants. Study material and data may be accessed by individuals from the participating Universities and National Health Service (NHS) Trusts, or regulatory authorities for auditing and monitoring purposes. Following publication of the trial results, we will make suitable arrangements for anonymised data to be available from the research team, in line with NIHR data sharing guidance.

IPD sharing plan summary

Available on request